Xadago® (safinamide) New Drug Application (NDA)
Accepted for Filing by the U.S. Food and Drug Administration (FDA)

Xadago® under review as an add-on therapy for patients with early- to late-stage Parkinson's disease

PDUFA date by December 29, 2015

Milan, Italy, March 2, 2015 – Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel central nervous system (CNS) and pain therapies, and its commercial and development partner, Zambon S.p.A., an international pharmaceutical company, announced today that the New Drug Application (NDA) for Xadago® (safinamide) has been accepted for filing by the U.S. Food and Drug Administration (FDA).

Under the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of December 29, 2015 to complete its review of the NDA.

The application covers the proposed use of Xadago® (safinamide) as add-on therapy in both early and mid-to-late stage Parkinson's disease patients who are inadequately managed on their current treatment.

"The acceptance of the NDA submission for review is based on extensive inputs received from the FDA during the last six months. This decision indicates that the process of review of the comprehensive efficacy and safety data on Xadago can proceed expeditiously, and brings Xadago® closer to becoming available for patients in the U.S.," said Ravi Anand, M.D., Newron's Chief Medical Officer. "If approved by the FDA, Xadago® will provide an innovative add-on treatment option for patients during all stages of Parkinson's disease."

"We are in late stage negotiations with interested potential partners for Xadago® in the U.S.", said Maurizio Castorina, Chief Executive Officer at Zambon. "And subject to FDA approval, Zambon expects the commercial launch of this New Chemical Entity by our North American partner in the first quarter of 2016."

The acceptance of the NDA by the FDA follows the Marketing Authorization by the EU Commission for Xadago® for the treatment of Parkinson´s disease in the EU, adopted on February 24, 2015.

About Parkinson's disease

Parkinson's disease (PD) is the second most common chronic progressive neurodegenerative disorder in the elderly after Alzheimer's disease, affecting 1-2% of individuals age 65 years and older worldwide. The prevalence of the PD is expected to grow in the next years due to the increase in the global population and advancements in healthcare that contribute to an aging population at increased risk for PD. The diagnosis of PD is mainly based on the observational criteria of muscular rigidity, resting tremor or postural instability in combination with bradykinesia. As the disease progresses, symptoms become more severe. Early-stage patients are more easily managed on levodopa (L-dopa). L-dopa remains the most effective treatment for PD, and over 75% of the patients with PD receive L-dopa. However, long term treatment with L-dopa leads to seriously debilitating motor fluctuations, i.e. phases of normal functioning (ON-time) and decreased functioning (OFF-time). Furthermore, as a result of the use of high doses of L-dopa with increasing severity of the disease, many patients experience involuntary movements known as L-dopa-Induced Dyskinesia (LID). As the disease progresses, more drugs are used as an add-on to what the patient already takes, and the focus is to treat symptoms while managing LID and the "off-time" effects of L-dopa. Most current therapies target the dopaminergic system that is implicated in the pathogenesis of PD, and most current treatments act by increasing dopaminergic transmission that leads to amelioration of motor symptoms. There is a growing belief that targeting non-dopaminergic systems may lead to improvements in PD symptoms such as dyskinesia that are not improved by current dopaminergic therapies.

About Xadago®

Xadago® (safinamide), an alpha-aminoamide, is currently being developed by Newron as an add-on therapy to dopamine agonists or to levodopa in patients with early or mid- to late-stage Parkinson's disease (PD). It has both dopaminergic and non dopaminergic activities, including selective and reversible inhibition of monoamine oxidase B (MAO-B), activity-dependent sodium channel antagonism and inhibition of glutamate release in vitro.

About Newron Pharmaceuticals

Newron (SIX: NWRN) is a biopharmaceutical company focused on the research and 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. 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, 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.

About Zambon

Zambon is a leading Italian pharmaceutical and fine-chemical multinational company that has earned a strong reputation over the years for high quality products and services. Zambon is well-established in 3 therapeutic areas: respiratory, pain and woman care, and is very strongly committed to its entry into the CNS space. Zambon SpA produces high quality products thanks to the management of the whole production chain which involves Zach (Zambon chemical), a privileged partner for API, custom synthesis and generic products. The Group is strongly working on the treatment of the chronic respiratory diseases as asthma and BPCO and on the CNS therapeutic area with Xadago® (safinamide) for the Parkinson treatment. Zambon is headquartered in Milan and was established in 1906 in Vicenza. Zambon is present in 15 countries with subsidiaries and more than 2,600 employees with manufacturing units in Italy, Switzerland, France, China and Brazil. Zambon products are commercialized in 73 countries.

For more information, contact

Media	**Investors and analysts**
Stefan Weber - CEO Phone: +39 02 6103 46 26 E-mail: pr@newron.com	Stefan Weber - CEO Phone: +39 02 6103 46 30 E-mail: ir@newron.com

UK/Europe Julia Phillips FTI Consulting Phone: +44 (0)20 3727 1000 **Zambon Company** Luca Primavera Phone: +39 02 66524491 Mobile: +39 335 7247417 Email: luca.primavera@zambongroup.com **Switzerland** Martin Meier-Pfister IRF Communications Phone: +41 43 244 81 40 **U.S.** Kristina Coppola LaVoieHealthScience Phone: +1 617 374 8800, Ext. 105 kcoppola@lavoiehealthscience.com	**U.S.** Donna LaVoie LaVoieHealthScience Phone: + 1 617 374 8800, Ext. 108 dlavoie@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.