



Safinamide New Drug Application (NDA) Re-submitted to the US Food and Drug Administration (FDA)

Milan, Italy, December 29, 2014 – Newron Pharmaceuticals S.p.A. (“Newron”), a research and development company focused on novel CNS and pain therapies, and its commercial and development partner Zambon S.p.A., an international pharmaceutical company, announced today that the NDA for safinamide has been re-submitted to the US FDA. This follows the announcement last week that the CHMP has given a positive opinion on safinamide for Europe.

The submission covers the indications “safinamide as add-on therapy to a stable dose of a single dopamine agonist” in early Parkinson’s disease patients and “safinamide as add-on therapy to levodopa alone or in combination with other Parkinson’s disease treatments” in mid-to late stage Parkinson’s disease patients.

The first submission of safinamide to the US FDA was made in May 2014. On review, the FDA issued a Refusal to File (RTF) letter based on organizational and navigational problems, largely due relating to the hyperlinking of tables, folders and the organization of the table of contents in the submission.

Ravi Anand, Newron’s CMO, stated: “Newron has been in frequent contact with the FDA to propose solutions to the technical issues and obtain their concurrence with the proposals. These discussions lead Newron to conclude that the RTF issues have been addressed in this submission.”

About 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 aged ≥ 65 years worldwide. The prevalence of the PD market 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 Parkinson’s disease. The diagnosis of PD is mainly based on 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 L-dopa. L-dopa remains as 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 safinamide

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 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. Following the submission of the Marketing Authorization Application (MAA) for safinamide for the treatment of Parkinson's disease to the European Medicines Agency (EMA) in December 2013, to Swissmedic in March, 2014 as well as the New Drug Application NDA to the US FDA, Newron is working towards global approval of the compound, together with its partners. Zambon Group 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. www.newron.com

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 details on Zambon please see: www.zambongroup.com

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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.

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