# Zambon and US Worldmeds partner to bring Newron Pharmaceuticals' Parkinson's disease treatment Xadago® (safinamide) to the U.S.

- *Xadago® (safinamide) is already approved in the EU and Switzerland, under review by the U.S. Food and Drug Administration*
- *Drug candidate has potential to assist the more than one million Americans living with Parkinson's*

**Milan, Italy – March 17, 2016 –** Zambon S.p.A., an international pharmaceutical company strongly committed to the central nervous system (CNS) therapeutic area, today announced a strategic agreement with US WorldMeds to commercialize Newron's lead compound, *Xadago® (safinamide),* for the treatment of Parkinson's disease in the U.S.

Zambon S.p.A. holds the global marketing rights for safinamide with the exception of Japan/Asia and has recently begun the commercialization of safinamide under the trade name Xadago® in the EU and Switzerland. The New Drug Application (NDA) for safinamide has been accepted for review by the U.S. Food and Drug Administration (FDA).

"We are really pleased to have signed this agreement for Xadago® with US WorldMeds" said Maurizio Castorina, CEO of Zambon S.p.A "It will help Zambon to fulfill the promise of bringing Xadago to patients with Parkinson's disease in the United States and highlights once again our commitment to the CNS therapeutic area".

Under the terms of the U.S. sub-licensing agreement, US WorldMeds will pay Zambon upfront, regulatory and commercial milestone payments as well as royalties on product sales. Newron Pharmaceuticals will receive from Zambon a milestone payment upon FDA approval and a share of upfront, milestones and royalty payments made by US WorldMeds to Zambon. Newron has been the sponsor of the clinical development for safinamide in all major countries of the world excluding Japan. US WorldMeds plans to focus more than 60 sales representatives launching Xadago in the U.S.

"US WorldMeds is thrilled to partner with Zambon and looks forward to introducing Xadago® in the U.S." said P. Breckinridge ("Breck") Jones, CEO of US WorldMeds. "Parkinson's disease has been a significant area of focus for our company for many years, and we look forward to leveraging our expertise in helping bring an exciting, new treatment option to the more than one million Americans with this condition."

Marketing authorization in the EU for safinamide was granted by the EU Commission in February 2015, and by Swissmedic in November 2015. Xadago® has been launched by Zambon in Germany, Spain and Italy, as well as in Switzerland. The New Drug Application (NDA) for safinamide has been accepted for review by the FDA with a PDUFA date of March 29, 2016.

"With US WorldMeds' focus on and knowledge of Parkinson's disease, we are confident that patients in the U.S. will have access to another innovative treatment option rapidly once Xadago® is approved," said Stefan Weber, CEO of Newron Pharmaceuticals.

**About Xadago® (safinamide)**

Safinamide is a new chemical entity with a unique mode of action including selective and reversible MAO-B-inhibition and blocking of voltage dependent sodium channels which leads to modulation of abnormal glutamate release. Clinical trials have established its efficacy in controlling motor symptoms and motor complications in the short term, maintaining this effect also in the long term (over 2 years). Results from long-term (24 months) double-blind controlled studies suggest that safinamide shows statistically significant effects on motor fluctuations (ON/OFF time) without increasing the risk of developing troublesome dyskinesia. This effect may be related to its dual mechanism acting on both the dopaminergic and the glutamatergic pathways. Safinamide is a once-daily dose and has no diet restrictions due to its high MAO-B/MAO-A selectivity. The New Drug Application (NDA) for Xadago® to the US FDA was accepted for filing by the US FDA, PDUFA date is March 29, 2016. Zambon has the rights to develop and commercialize Xadago® globally, excluding Japan and other key territories where Meiji Seika has the rights to develop and commercialize the compound.

References:
Two-year, randomized, controlled study of safinamide as add-on to levodopa in mid to late Parkinson's disease. Borgohain, Rupam; Szasz, Jozsef; Stanzione, Paolo; Meshram, Chandrashekhar; Bhatt, Mohit H et al. (2014) *Movement disorders : official journal of the Movement Disorder Society* vol. 29 (10) p. 1273-80.

Anand R: Safinamide is associated with clinically important improvement in motor symptoms in fluctuating PD patients as add-on to levodopa (SETTLE). 17th International Congress of Parkinson's Disease and Movement Disorders, Sydney, Australia, June 16-20, 2013.

**About Parkinson's disease**

Parkinson's disease 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 PD. 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.

References:
BMC Oertel. European Handbook of Neurological Management, Vol1, Chapter 14 & 15, 2011.
NICE PD guideline, 2006.

**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 women's care, and is very strongly committed to its entry into the CNS space. Zambon S.p.A 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. 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

**About US WorldMeds**

US WorldMeds is a specialty pharmaceutical company dedicated to developing, licensing and commercializing unique and significant specialty pharmaceuticals that address unmet medical needs or overcome limitations of existing products. Through sound science and targeted commercialization, the Kentucky-based company continually strives to identify specialty and orphan products for diseases with limited patient populations. US WorldMeds' portfolio includes Revonto® (dantrolene sodium for injection) for the treatment of malignant hyperthermia, MYOBLOC® (rimabotulinumtoxinB) Injection for the treatment of cervical dystonia in adults and APOKYN® (apomorphine hydrochloride injection) for the acute, intermittent treatment of hypomobility, "off" episodes associated with advancing Parkinson's disease. In addition, US WorldMeds is working on the development of a non-narcotic drug product (Lofexidine) for the treatment of opiate withdrawal symptoms. For more information about US WorldMeds, visit www.usworldmeds.com.

**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) for the treatment of Parkinson's disease was granted by the EU Commission in February 2015, followed by Swissmedic's marketing authorization for Switzerland in November 2015. The drug has been launched by Newron's partner Zambon in the first key EU countries Germany, Spain and Italy, as well as in Switzerland. The New Drug Application (NDA) has been accepted for review by the FDA, PDUFA date March 29, 2016. 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. They include Sarizotan for patients with Rett Syndrome, for which Newron received Orphan Drug Designation in both the US and the EU, ralfinamide for patients with specific rare pain indications, and NW-3509 as potentially the first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.

**For more information**

| Media | Investors and Analysts |
|---|---|
| **Zambon**<br>Luca Primavera - CCO<br>Phone: +39 02 66524491<br>Mobile: +39 335 7247417<br>Email: luca.primavera@zambongroup.com<br><br>**Italy**<br>Milva Naguib<br>Phone: +39 02 66524095<br>Mobile: +39 3459215675<br>Email: milva.naguib@zambongroup.com<br><br>**US WorldMeds**<br>P. Breckinridge Jones – CEO<br>Phone : +1 502.815.8101<br>Email : pbj@usworldmeds.com<br><br>**Newron**<br>Stefan Weber - CEO<br>Phone: +39 02 6103 46 30<br>E-mail: ir@newron.com<br><br>**UK/Europe**<br>Julia Phillips<br>FTI Consulting<br>Phone: +44 (0)20 3727 1000<br><br>**Switzerland**<br>Martin Meier-Pfister<br>IRF Communications<br>Phone: +41 43 244 81 40<br><br>**Germany**<br>Anne Hennecke<br>MC Services AG<br>Phone: +49 211 52925222<br>anne.hennecke@mc-services.eu<br><br>**U.S.**<br>Alison Chen<br>LaVoieHealthScience<br>Phone: +1 617 374 8800, Ext. 104<br>achen@lavoiehealthscience.com | **Newron**<br>Stefan Weber - CEO<br>Phone: +39 02 6103 46 30<br>E-mail: ir@newron.com<br><br>**Germany**<br>Anne Hennecke<br>MC Services AG<br>Phone: +49 211 52925222<br>anne.hennecke@mc-services.eu<br><br>**U.S.**<br>Beth Kurth<br>LaVoieHealthScience<br>Phone: +1 617 374 8800, Ext. 109<br>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.