



# ZAMBON LAUNCHES XADAGO ▼® (SAFINAMIDE) IN THE U.K. FOR PATIENTS WITH MID- TO LATE-STAGE PARKINSON'S DISEASE

- Zambon today announces the availability in the U.K. of Xadago® (safinamide) for the
  treatment of adult patients with idiopathic Parkinson's disease (PD) as an add-on
  therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other
  Parkinson's disease medicines in mid-to late-stage fluctuating patients
- Safinamide is a new chemical entity with dopaminergic and non dopaminergic actions

**Milan, Italy – May 23, 2016 –** Zambon S.p.A., an international pharmaceutical company strongly committed to the central nervous system (CNS) therapeutic area, and its partner 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 nervous system (CNS) and pain, today announced the availability of Xadago® (safinamide) in the United Kingdom.

Andrew Lees, MD FRCP, FMedSci, Professor of Neurology, (The National Hospital for Neurology and Neurosurgery, Queen Square and Emeritus Director, Reta Lila Weston Institute of Neurological Studies, University College London, Institute of Neurology) said: "After 10 years with no new drugs for Parkinson's disease I welcome the addition of another effective treatment option for patients".

Maurizio Castorina, CEO of Zambon S.p.A. said: "We are committed to developing innovative therapies for patients suffering from PD and other central nervous system diseases. Xadago® offers PD patients a novel therapeutic option in the treatment of this progressive disease".

The U.K is the latest country launching Xadago®, which is also available in seven other countries: Germany, Switzerland, Spain, Italy, Belgium, Denmark, and Sweden.

▼ 'This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects.'

# 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, with data supporting this effect over 2 years. Results from 6 month 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. Safinamide is a once-daily dose and has no diet restrictions. 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. The rights to develop and commercialize Xadago® in the USA have been granted to US WorldMeds, by Zambon.

### 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

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 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.

## 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 woman care, and is very strongly committed to its entry into the CNS space. Zambon 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 19 countries with subsidiaries and almost 2,700 employees with manufacturing units in Italy, Switzerland, France, China and Brazil. Zambon products are commercialized in 84 countries.

## **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. 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.

### **Further Information**

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

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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.

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