



ZAMBON LAUNCHES XADAGO® (SAFINAMIDE) IN SWITZERLAND FOR PATIENTS WITH PARKINSON'S DISEASE

Milan, Italy – January 12, 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"), a research and development company focused on novel CNS and pain therapies, today announced the launch of Xadago® (safinamide) in Switzerland, the second market after Germany. Swissmedic approved Xadago® (safinamide) on Nov. 12 as add-on therapy to levodopa (L-dopa) alone or in combination with other therapies for patients with Parkinson's disease (PD) in mid-to late-stage and motor fluctuations.

"We are pleased that, so soon after the approval by Swissmedic, patients with Parkinson's disease in Switzerland now have access to Xadago®, an innovative, add-on treatment option that has shown meaningful improvements in 'ON and OFF time' without any increase in Parkinson's disease symptoms such as dyskinesia," said Maurizio Castorina, CEO of Zambon S.p.A. "Additionally, we are pleased with the positive reception of Xadago® in Germany and are finalizing preparations for a series of additional launches in EU countries during 2016."

"It is truly rewarding to see Xadago® available to patients in Germany and Switzerland, and we look forward to patients with Parkinson's disease around the world having access to this important therapeutic option," 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, use-dependent Na channels blockade and Ca channels modulation which lead to modulation of abnormal glutamate release. Clinical trials have unequivocally 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 significant effects on motor fluctuations (ON/OFF time) without increasing the risk of developing troublesome dyskinesia. This positive effect may be related to its dual mechanism acting on both the dopaminergic and the glutamatergic pathways. Safinamide is well tolerated with a favourable side-effect profile and is easy to use: once-daily dose, no need of LD adjustment, no major drug—drug interactions, no diet restrictions due to its higher MAO-B/MAO-A selectivity.

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 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 19 countries with subsidiaries and almost 2,700 employees with manufacturing units in Italy, Switzerland, France, China and Brazil. Zambon productes are commercialized in 84 countries.

For details on Zambon please see: www.zambongroup.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 the launch by Zambon in the first key EU country - Germany - in May 2015. The New Drug Application (NDA) has been accepted for review by the FDA, as reported in March 2015. In November 2015, Swissmedic has granted marketing authorization to Zambon, Newron's partner. 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 additional information, please visit https://www.newron.com.

Further Information

Media	Investors and Analysts
Zambon Luca Primavera - CCO Phone: +39 02 66524491 Mobile: +39 335 7247417 Email: luca.primavera@zambongroup.com Giovanna Giacalone	Newron Stefan Weber - CEO Phone: +39 02 6103 46 30 E-mail: ir@newron.com
Email: ggiacalone@webershandwick.com Ph: +39 3497738681 Weber Shandwick	
Germana Mancino Email: gmancino@webershandwick.com Ph: +39 3492625439 Weber Shandwick	
Newron Stefan Weber - CEO Phone: +39 02 6103 46 26 E-mail: pr@newron.com	
UK/Europe Julia Phillips FTI Consulting Phone: +44 (0)20 3727 1000	
Switzerland Martin Meier-Pfister IRF Communications Phone: +41 43 244 81 40	
Germany Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu	Germany Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu

U.S.
David Connolly
LaVoieHealthScience
Phone: +1 617 374 8800, Ext. 108
dconnolly@lavoiehealthscience.com

U.S.
Kristina Coppola
LaVoieHealthScience
Phone: +1 617 374-8800, Ext. 105
kcoppola@lavoiehealthscience.com

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