ZAMBON LAUNCHES XADAGO® (SAFINAMIDE) IN ITALY FOR PATIENTS WITH MID- TO LATE-STAGE PARKINSON'S DISEASE

- *Zambon is announcing today the availability and reimbursement on the Italian market of Xadago® (safinamide) as an add-on to levodopa alone or in combination with other Parkinson's Disease (PD) medications*

- *Xadago® (safinamide) is the result of the Italian research excellence*

Milan – Feb. 29, 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 Italy for the treatment of mid- to late-stage Parkinson's disease (PD). Following the launch in Switzerland, Germany and Spain, Xadago® (safinamide) is now available in Italy as add-on therapy to a stable dose of levodopa (L-dopa) alone or in combination with other PD therapies for mid-to late-stage fluctuating patients.

Prof. Fabrizio Stocchi from IRCSS S. Raffaele, Rome, declared that *"safinamide represents an important option for patients with PD already treated with L-dopa alone or with other therapeutic combinations. Its dopaminergic and non dopaminergic properties introduce a novelty within the drugs for PD treatment."* Prof. Stocchi added: *"Safinamide has been demonstrated to significantly increase on time with no, or non-troublesome dyskinesias in addition to an improvement of motor functions (UPDRS III). Studies performed in patients on L-Dopa have demonstrated its efficacy in benefiting both short-term (6 months) and long-term (up to 24 months) quality of life outcomes. Safinamide has been investigated in double blind, placebo-controlled studies of up to 24 months' duration, where it showed a good safety profile with maintenance of the clinical benefits*."

Maurizio Castorina, CEO of Zambon SpA said: *"The launch of Xadago® in Italy makes us particularly proud because it is the result of Italian research excellence and a major step forward in the treatment of this progressive disease. We are committed to developing innovative therapies for patients suffering from PD and other central nervous system diseases and we look forward to launching this new chemical entity in other European countries in the near future."*

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 over 2 years. Results from 24 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. 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
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 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 products 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. 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 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.
For more information, please visit: **www.newron.com**

Further Information

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