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

- *Zambon today announces the availability of Xadago® (safinamide) in Portugal as an add-on to levodopa alone or in combination with other Parkinson's disease (PD) medications in mid- to late-stage PD*
- *Safinamide is a new chemical entity with a unique dopaminergic and non-dopaminergic mechanism of action, providing control of motor symptoms and motor complications both in the short and long term*
- *Xadago® (safinamide) has now been launched in 11 European Union countries, Switzerland, and was recently approved by the US Food and Drug Administration*

Milan – April 10, 2017 – 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 launch of Xadago® (safinamide) in Portugal for the treatment of mid- to late-stage Parkinson's disease (PD).

Safinamide is a new chemical entity with a unique dopaminergic and non-dopaminergic mechanism of action (MoA), providing a balanced control of motor symptoms and motor complications. It is now available in Portugal 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. Joaquim Ferreira, Professor of Neurology and Clinical Pharmacology at the Faculty of Medicine, University of Lisbon, commented: "*Safinamide's unique dual mechanism of action makes it a valuable treatment option for fluctuating PD patients".*

Roberto Tascione, CEO of Zambon, said: "*Today's launch of* Xadago® *in Portugal is a great step forward for patients who urgently need a novel treatment option for Parkinson's disease. Zambon is committed to paving the way for the development of innovative therapies for patients suffering from Parkinson's disease and other diseases of the central nervous system, with the potential to raise the standard of care."*

With the addition of Portugal, Xadago® is now available in twelve European countries: Germany, Switzerland, Spain, Italy, Belgium, Denmark, Sweden, UK, Luxembourg, the Netherlands and Norway. In addition to launch in Europe, on March 21, 2017 the US Food and Drug Administration (FDA) approved the use of Xadago® for the treatment of Parkinson's disease as add-on therapy to levodopa/carbidopa

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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. 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 women's health, and is very strongly committed to its entry into the CNS space with Xadago® (safinamide) for the treatment of Parkinson's disease and rare diseases with Promixin® in cystic fibrosis. Zambon is headquartered in Milan and was established in 1906 in Vicenza. Zambon is present in 19 countries with subsidiaries and almost 2,800 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. For more information, please visit: **www.newron.com**

Further Information

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