PARKINSON'S DISEASE (PD):
EU COMMISSION APPROVES XADAGO® (SAFINAMIDE)
FOR MID-LATE STAGE PD PATIENTS

The European Commission approves the use of XADAGO® as add-on to L-dopa alone or in combination with other PD medications in mid-late stage PD patients with motor fluctuations

Milan, 26 February 2015 – 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, announced today that the European Commission approved the use of Xadago® (safinamide) for the treatment of idiopathic Parkinson's disease (PD). Xadago® has been approved for mid-to late-stage fluctuating patients as add-on therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other PD medicinal products. The decision follows the Positive Opinion adopted by the Committee for Medicinal Products for Human Use (CHMP) on December 18th, 2014 and is applicable to all 28 European Union member countries, as well as Iceland, Liechtenstein and Norway.

"*Levodopa, still the gold standard of symptomatic efficacy in the treatment of Parkinson's disease, in its long-term use is associated with motor complications which still constitute a major unmet medical need in PD therapy* – stated Prof. Werner Poewe, Director of the Department of Neurology, Innsbruck Medical University and University Hospital. "*Targeting non-dopaminergic systems might be an alternative approach to improve and control such motor complications, enhancing efficacy and removing the need for further increases in levodopa dose, that has been shown to worsen motor fluctuations.*"

Ravi Anand, Newron's CMO, commented: "We're extremely pleased to see the European Commission's approval, providing a next generation, innovative add-on treatment option to PD patients. Xadago® (safinamide) is the first add-on treatment for PD showing both

rapid onset of efficacy and improvements in 'ON and OFF Time', without any increase in dyskinesia for at least two years, compared with 'Standard of Care', as demonstrated in a double-blind trial in patients receiving optimized treatment for PD. The compound's dual mechanism includes highly selective, reversible inhibition of MAO-B, and state and use-dependent blockade of sodium channels; the latter action leads to inhibition of stimulated release of glutamate. As excessive glutamate release is implicated in the etiology of dyskinesia, Xadago® (safinamide) could prevent or attenuate L-dopa induced dyskinesia in PD patients."

"*We are particularly proud of this result* – said Maurizio Castorina, CEO of Zambon S.p.A. *– since it is another acknowledgement of the commitment of Zambon in answering the unmet needs of PD patients. This is the first time in 10 years that a New Chemical Entity (NCE) receives the EC approval for the treatment of PD patients and we are really excited to be a part of it. We will now proceed with the marketing authorizations in the EU countries, starting in the first half of 2015, to give the opportunity to all the patients in need to receive this therapy".*

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. The New Drug Application (NDA) for Xadago® to the US FDA was resubmitted by December 26, 2014. In March 2014, Zambon submitted an MAA to Swissmedic. Zambon has the rights to develop and commercialize Xadago® globally, exluding Japan and other key territories where Meiji Seika has the rights to develop and commercialize the compound.

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 15 countries with subsidiaries and more than 2,600 employees with manufacturing units in Italy, Switzerland, France, China and Brazil. Zambon productes are commercialized in 73 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, sNN0031 for patients with Parkinson's disease, non-responsive to oral drug treatments, sNN0029 for patients with ALS 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**

For further information

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