

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

*Germany is the first country in which Xadago® is available as an add-on to levodopa alone and in combination with other PD medications*

**Milan – May 15, 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, today announced the launch of Xadago® (safinamide) in Germany for the treatment of mid- to late-stage Parkinson's disease (PD). Germany is the first country in which Xadago®, which has been approved 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, is launched.

**Prof. Heinz Reichmann, Chair Dept. Neurology University of Dresden** stated: *"When a Parkinson's disease patient is no longer optimally controlled with levodopa, Xadago® may become the first choice as add-on to levodopa, because it has shown a balanced control of motor symptoms and motor complications. These benefits have been proved at six months and maintained over two years. The reason why is its unique mechanism of action, dopaminergic and non dopaminergic targets. Xadago® uniquely combines the modulation of the dopamine and glutamate systems, which in add-on therapy may maximise motor symptom control in Parkinson's disease without worsening motor complications. In due course, most Parkinson's disease patients worldwide could benefit from the advantages of Xadago."*

**Maurizio Castorina, CEO of Zambon SpA** said: *"The launch of Xadago® in Germany represents a significant milestone in Zambon's pharmaceutical business and in particular our increased commitment to R&D innovation. The launch of Xadago® is a major step forward in the treatment of Parkinson's disease, and Zambon is fully committed to invest further for the benefit of all Parkinson's disease patients."*

**Stefan Weber, CEO of Newron** commented: *"We are pleased that patients with Parkinson's disease in Germany now have access to a much needed innovative add-on treatment option. Xadago® has shown meaningful improvements in 'ON and OFF time', without any increase in symptoms such as dyskinesia. As Newron and partner Zambon continue to*

*pursue additional marketing authorizations, we look forward to seeing access of Xadago® expanded to patients in other regions in Europe and the U.S.“*

#### **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 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 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 Dec. 29, 2015. In March 2014, Zambon submitted an MAA to Swissmedic. 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.

#### **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 women's 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 COPD 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 products are commercialized in 73 countries.

For details on Zambon please see: [www.zambongroup.com](http://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](http://www.newron.com)

## Further Information

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