



## **Swissmedic approves Xadago® (safinamide) for use in Parkinson's Disease**

*Milan, November 13, 2015* – Zambon S.p.A., an International Pharmaceutical Company with a strong commitment in central nervous system (CNS) diseases, and its partner Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel CNS and pain therapies, today announced that Swissmedic on November 12, 2015, has approved Xadago® (safinamide) as add-on therapy to levodopa (L-dopa) alone or in combination with other PD therapies for patients with Parkinson's Disease in mid-to late-stage and motor fluctuations.

The approval in Switzerland was preceded by the marketing authorization throughout the European Union by the Commission of the EU, in February 2015. Xadago was also accepted for review by the US FDA and has a current PDUFA date of March 29, 2016.

Maurizio Castorina, CEO of Zambon, stated: "This approval by Swissmedic is further evidence of the acceptance of the benefits offered by Xadago® (safinamide) by another regulatory authority. We keep on working to ensure this new chemical entity will be available to all the patients in need of innovative therapies in Parkinson's Disease."

Stefan Weber, CEO of Newron, added: "We are delighted that PD patients in Switzerland will now have access to this innovative treatment offering unique benefits."

### **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 products are commercialized in 84 countries.  
For details on Zambon please see: [www.zambogroup.com](http://www.zambogroup.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 March 2014, Zambon, Newron's partner, submitted an MAA to Swissmedic. 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 <http://www.newron.com>.