ZAMBON ANNOUNCES APPROVAL AND ARTG LISTING OF SAFINAMIDE IN AUSTRALIA FOR TREATMENT OF PATIENTS WITH PARKINSON'S DISEASE

FURTHER REGULATORY SUBMISSIONS ONGOING WITH AUTHORITIES WORLDWIDE

Milan, Italy – November 30, 2018 – 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 and peripheral nervous system, today announced the recent approval of Xadago®/safinamide in Australia by the Therapeutic Goods Administration (TGA) of the Australian Government Department of Health for the treatment of adult patients with fluctuating idiopathic Parkinson's disease (PD) as add-on therapy to a regimen that includes levodopa (L-Dopa).

Xadago has been registered on the Australian Register of Therapeutic Goods (ARTG), which is the formal requirement for supply and marketing of the medicine. Under a partnership agreement with Zambon, Seqirus, a global leader in influenza prevention and a leading provider of essential vaccines and pharmaceuticals in Australia and New Zealand, has undertaken the registration with the Australian authorities and will now work to supply Xadago.

Roberto Tascione, CEO of Zambon, said: "*The approval of* safinamide *in Australia is a great step forward for patients who need new treatment options for Parkinson's disease. Our partner Seqirus is committed to launch this product and make this innovative therapy available to patients suffering from Parkinson's disease in Australia."*

Xadago/safinamide is commercialized by Newron's partner Zambon; it is approved in Switzerland as well as the European Union (currently available in 13 of its member states). US WorldMeds holds the commercialization rights in the USA, where the compound has been launched in July 2017. Meiji Seika has the rights to develop and commercialize safinamide in Japan and other key Asian territories; Meiji Seika Pharma has filed for marketing approval of safinamide with the Japanese Pharmaceutical and Medical Device Agency in October 2018. Further dossiers for marketing authorization are currently under review in Brazil, Canada, Colombia and Israel. Zambon is also currently leading discussions on additional distribution agreements in Europe and the Middle East.

About safinamide (Xadago®)
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 Asian territories where Meiji Seika has the rights to develop and commercialize safinamide. 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, Vol 1, Chapter 14 & 15, 2011.
NICE PD guideline, 2006.

About Zambon
Zambon is a multinational pharmaceutical and fine-chemical company that focuses on innovation and development with the aim to improve the quality of people's health and patients' lives. Based on a valuable heritage but strongly focused on the future, its goal is to improve people's health through the development of innovative and quality medicines. Zambon products are commercialized in 86 countries. The company has 20 subsidiaries in three different Continents – Europe, America and Asia – and owns manufacturing units in Italy, Switzerland, France, China and Brazil. The company today has a strong focus on the treatment of rare diseases and specialties, such as Parkinson's disease and Cystic Fibrosis, and it's well-established in 3 therapeutic areas: respiratory, pain and women's care. Zambon was established in 1906 in Italy and today counts around 2,700 employees all over the world. For details on Zambon please visit **www.zambon.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 and peripheral nervous system. The Company is headquartered in Bresso near Milan, Italy. Xadago®/safinamide has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland and the USA, and is commercialized by Newron's Partner Zambon. US WorldMeds holds the commercialization rights in the USA. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. In addition to Xadago®/safinamide 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 Evenamide 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**

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