Valeo Pharma and Zambon form partnership for Parkinson's Disease Treatment Xadago® (safinamide) in Canada

- *Valeo Pharma and Zambon announce a partnership in Canada which grants Valeo Pharma exclusive rights to commercialise Zambon's Parkinson's disease product, licensed from Newron*
- *New treatment option for estimated 100,000 Canadians living with Parkinson's disease*
- *Xadago® (safinamide) has been launched in the European Union, Switzerland, and it has recently been approved by the U.S. Food and Drug Administration in the U.S.A.*
- *Valeo Pharma to be responsible for registering and launching Xadago® in Canada*

Montreal, April 11, 2017 – Zambon S.p.A., an international pharmaceutical company strongly committed to the central nervous system (CNS) therapeutic area, and Valeo Pharma Inc., a specialty pharmaceutical company dedicated to registering and launching innovative prescription products in Canada, today announced a strategic agreement to commercialize Xadago® (safinamide) for the treatment of Parkinson's disease in Canada.

Under the terms of the agreement, Valeo Pharma will be responsible for all regulatory, sales and marketing, quality, and distribution activities in Canada. Valeo Pharma will pay Zambon upfront, regulatory and commercial milestone payments as well as royalties on product sales.

"O*n approval, Xadago® will be the first new oral treatment in almost 15 years to address this serious condition in Canada*," said Steve Saviuk, President of Valeo Pharma. "*We look forward to bringing this important new treatment option to more than 100,000 Canadians living with Parkinson's, and adding to our growing portfolio of prescription medications addressing major neurodegenerative diseases*."

Roberto Tascione, CEO of Zambon said "*We are very pleased to have signed our agreement with Valeo Pharma, a company with an excellent track record in bringing innovative products to market. Entering Canada is an important step forward in the acceptance of safinamide for patients with PD already treated with L-dopa or other therapeutic combinations".*

Xadago® (safinamide) has been launched by Zambon in Germany, Switzerland, Spain, Italy, Belgium, Denmark, Sweden, UK, Luxembourg, the Netherlands and Norway. Zambon S.p.A. holds the global marketing rights for safinamide with the exception of Japan/Asia. Marketing authorization in the EU for safinamide was granted by the EU Commission in February 2015, and by Swissmedic in November 2015. On March 21, 2017 the Food and Drug Administration (FDA) has approved the use of Xadago® (safinamide) for the treatment of Parkinson's disease as add-on therapy to levodopa/carbidopa.

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 Asian territories where Meiji Seika Pharma has the rights to develop and commercialize the compound. The rights tocommercialize 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 Valeo Pharma
Valeo Pharma is a specialty pharmaceutical company dedicated to the registration and launch of innovative prescription products in Canada. With a focus on neurodegenerative diseases, kidney diseases, and hospital products, Valeo Pharma has a growing portfolio of innovative products that includes Synacthen (tetracosactide) and M-Eslon (morphine sulfate). Headquartered in Montreal, Quebec, Valeo Pharma has a full complement of capabilities to license, register, launch, and market innovative medications for Canadian patients. For more information, please visit www.valeopharma.com.

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.**

For more information

Media
Zambon Luca Primavera - CCO Phone: +39 02 66524491 Mobile: +39 335 7247417 Email: luca.primavera@zambongroup.com **Italy** Milva Naguib Phone: +39 02 66524095 Mobile: +39 3459215675 Email: milva.naguib@zambongroup.com **Valeo Pharma** Steve Saviuk – President and CEO Phone : +1 514 693-8830 Email : saviuk@valeopharma.com