

## Valeo Pharma and Zambon announce the approval of Onstryv® (safinamide) for Canada

- Valeo Pharma and Zambon previously announced a partnership which grants Valeo Pharma exclusive Canadian rights to commercialize safinamide (known as Onstryv® in Canada and Xadago® in the rest of the world).
- New treatment option for estimated 100,000 Canadians living with Parkinson's Disease.
- Safinamide has been launched in 13 European countries, Switzerland and the U.S.A., and has recently been approved in Australia.

**January 15, 2019** –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 commercializing innovative prescription products in Canada, today announce the approval of Onstryv® (safinamide) for the treatment of Parkinson's Disease in Canada.

Under the terms of the agreement with Zambon, Valeo Pharma is responsible for all regulatory, quality, sales and marketing, and distribution activities in Canada.

*“There is a growing need for new treatments to manage Parkinson's Disease and Onstryv® provides an important option for patients that require better control of their symptoms. We look forward to launching the first new oral treatment for Parkinson's Disease in over a decade to Canadian patients in need of a new therapeutic choice,”* said Steve Saviuk, Chief Executive Officer of Valeo.

Valeo Pharma expects the Canadian launch of safinamide to occur during the first half of 2019.

Roberto Tascione, CEO of Zambon said *“The approval of safinamide in Canada is a step forward for patients who need new treatment options for Parkinson's Disease. Our mission is to make this medication available to as many PD patients worldwide as possible.”*

Parkinson's Disease is a progressive neurological disease involving the loss of dopamine-producing neurons in the brain. While tremors are the best known symptom, Parkinson's Disease also causes slowed movement, rigid muscles, impaired posture and balance, and speech and writing difficulties. An estimated 100,000 Canadians are affected and the number of patients is expected to grow significantly over the next thirty years as the population continues to age.

**About safinamide**

Safinamide (known as *Onstryv*® in Canada and *Xadago*® in the rest of the world) is a new chemical entity with a mode of action including selective and reversible MAO-B-inhibition. Clinical trials have established its efficacy in controlling motor symptoms and motor complications in the short term, and data suggest this effect is maintained over 2 years. Results from 24 month double-blind controlled studies suggest that safinamide shows effects on motor fluctuations (ON/OFF time) without increasing the risk of developing troublesome dyskinesia. Safinamide is a once-daily dose and has no diet restrictions due to its high MAO-B/MAO-A selectivity. Zambon acquired rights from Newron Pharmaceuticals ([www.newron.com](http://www.newron.com)) 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 Valeo Pharma**

Valeo Pharma is a specialty pharmaceutical company dedicated to the commercialization of innovative prescription products in Canada. With a focus on neurodegenerative diseases, woman's health, and oncology and supportive care, Valeo Pharma has a growing portfolio of innovative products and a platform to properly manage these products through all stages of commercialization. Headquartered in Kirkland, Quebec, Valeo Pharma has all capabilities internally to register and market health care solutions for Canadian patients. For more information, please visit [www.valeopharma.com](http://www.valeopharma.com)

**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](http://www.zambon.com)

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