



Newron Pharmaceuticals: Commercialization partner Zambon together with Valeo Pharma announce the approval of Onstryv® (safinamide) for Parkinson's disease in Canada

Milan, Italy – January 16, 2019 – 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, is pleased to note that its partner Zambon S.p.A, together with Valeo Pharma Inc., have announced the approval of Onstryv® (safinamide) for the treatment of Parkinson's disease in Canada.

The full text of the announcement from Zambon S.p.A and Valeo Pharma Inc. is as follows:

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) 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

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

For more information, please contact:

Zambon

Valentina Saffioti - Global Head of Pharma Communication

+39 0266524508 - valentina.saffioti@zambongroup.com

Valeo Pharma

Steve Saviuk - President and CEO

+1 514 693-8830 - saviuk@valeopharma.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

For more information, please contact:

Stefan Weber – CEO
+39 02 6103 46 26
pr@newron.com

UK/Europe

Julia Phillips / Natalie Garland-Collins, FTI Consulting
+44 20 3727 1000
SCnewron@fticonsulting.com

Switzerland

Martin Meier-Pfister, IRF Communications
+41 43 244 81 40
martin.meier-pfister@irfcom.ch

Germany/Europe

Anne Hennecke, MC Services
+49 211 52925222
anne.hennecke@mc-services.eu

USA

Paul Sagan, LaVoieHealthScience
+1 617 374 8800, Ext. 112
psagan@lavoiehealthscience.com

Important Notices

This document contains forward-looking statements, including (without limitation) about (1) Newron's ability to develop and expand its business, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates and reduce costs (including staff costs), (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's anticipated future revenues, capital expenditures and financial resources, and (4) assumptions underlying any such statements. In some cases, these statements and assumptions can be identified by the fact that they use words such as "will," "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "target," and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron's strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements. By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions. Newron may not 5/5 actually achieve the plans, intentions or expectations disclosed in forward-looking statements, and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron's research programmes, development activities,



commercialisation plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions. Newron does not undertake any obligation to publicly update or revise forward-looking statements except as may be required by applicable regulations of the SIX Swiss Exchange, where the shares of Newron are listed. This announcement is not an offer for sale of securities in the United States, Canada, Australia or Japan or any other jurisdiction where such an offer or solicitation would otherwise be unlawful. The securities referred to herein may not be sold in the United States absent registration or an exemption from registration under the U.S. Securities Act of 1933, as amended. Newron does not intend to register any of its securities in the United States or to conduct a public offering of its securities in the United States. This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron and no part of this document shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.