



Meiji Seika and Eisai enter into a collaboration for the development and commercialization of safinamide in Parkinson's disease for Japan and Asia

Milan, Italy, April 5, 2017 – 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 nervous system (CNS) and pain, is pleased to note the news from its partner Meiji Seika Pharma Co., Ltd., that it has entered into a collaboration with Eisai Co., Ltd.

The full text of the announcement from Meiji Seika and Eisai is as follows:

EISAI AND MEIJI ENTER INTO LICENSING AGREEMENT CONCERNING PARKINSON'S DISEASE DRUG SAFINAMIDE IN JAPAN AND ASIA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, “Eisai”) and Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo; CEO: Daikichiro Kobayashi, “Meiji”) announced today that they have entered into a license agreement for the commercialization of safinamide (development code: ME2125) for the treatment of Parkinson's disease in Japan and Asia. Safinamide is currently under clinical development by Meiji in Japan.

Under the agreement, Eisai will obtain exclusive rights to safinamide to market in Japan and to develop and market in Asia (seven countries*). Meiji will continue the clinical trials that it is currently conducting and submit a manufacturing and marketing authorization application for the drug in Japan. Meanwhile, Eisai will conduct clinical trials for seeking regulatory approval, and make the applications in Asia. Meiji will manufacture and supply the product of safinamide to Eisai for Japan and Asia. Furthermore, Meiji will receive an upfront payment from Eisai, as well as developmental milestone and sales royalty payments under the agreement.

Parkinson's disease is a neurodegenerative disease which causes motor impairment, including shaking in the limbs, muscular rigidity and brachybasia. It is caused by degeneration of the dopamine nervous system, which leads to a shortage of dopamine, a neurotransmitter in the brain.

According to a survey by the Ministry of Health, Labour and Welfare, the number of patients suffering from Parkinson's disease in Japan numbered 163,000 in 2014¹, with the number of patients increasing due to the aging of the population.²

Levodopa is widely used to treat Parkinson's disease by replenishing the brain's supply of dopamine. However, as the disease progresses, levodopa's duration of effect (“on” time) decreases, and there are cases of Parkinson's disease symptoms returning before the next dose (“wearing-off” phenomenon). To prevent the “wearing-off” phenomenon, combination therapy with a drug that has a different mechanism of action to levodopa is administered.

Safinamide is a selective monoamine oxidase B (MAO-B) inhibitor, which reduces the degradation of excreted dopamine, helping to maintain the density of dopamine in the brain. Additionally, safinamide blocks sodium ion channels and inhibits glutamate release, and as

such, has potential as a new Parkinson's disease treatment which possesses both dopaminergic and non-dopaminergic mechanisms. Global clinical trials of safinamide in combination with levodopa for the treatment of mid- to late-stage Parkinson's disease showed extended "on" time, and an improvement in motor function.³

Safinamide was discovered and developed by Newron Pharmaceuticals S.p.A. (Headquarters: Italy, Milan, "Newron"). In 2011, Newron entered into a licensing agreement with Meiji, granting Meiji exclusive rights to development, manufacture and commercialize the drug in Japan and Asia. Safinamide is marketed under the name "Xadago" in eleven countries in Europe, and on March 21, 2017, was approved by the U.S. Food and Drug Administration. In Japan, Meiji is currently conducting Phase II/III trials for safinamide in combination with levodopa.

Through this agreement, Eisai and Meiji will make further contributions to address the diversified needs of, and increase the benefits provided to, Parkinson's disease patients and their families.

* South Korea, Taiwan, Brunei, Cambodia, Laos, Malaysia, and the Philippines

Notes to editors

1. About Eisai Co., Ltd.

Eisai Co., Ltd. defines its corporate mission as "giving first thought to patients and their families and to increasing the benefits health care provides," which we call our human health care (hhc) philosophy. With approximately 10,000 employees working across our global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to realize our hhc philosophy by delivering innovative products to address unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

Furthermore, we invest and participate in several partnership-based initiatives to improve access to medicines in developing and emerging countries.

For more information about Eisai Co., Ltd., please visit www.eisai.com/.

2. About Meiji Seika Pharma

In order to protect and improve people's health and lives, Meiji Seika Pharma, as a "Speciality and Generic Pharmaceuticals Company", runs its pharmaceutical business in the two main fields, infectious disease and central nervous system disorders, as well as generic drugs. Meiji Seika Pharma strives to respond to diversified medical needs and contributes to the well-being of people worldwide.

For details, please visit its corporate website:

<http://www.meiji.com/global/about-us/corporate-profile/meiji-seika-pharma/>

¹ Patient Survey 2014 (Disease and Injury) by Statistics and Information Department, Minister's Secretariat, Ministry of Health, Labour and Welfare

² Japan Intractable Diseases Information Center <http://www.nanbyou.or.jp/>

³ Borgohain R et al. Randomized Trial of Safinamide Add-On to Levodopa in Parkinson's Disease With Motor Fluctuations. *Mov Disord.* 2014 Feb;29(2):229-37

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, with a subsidiary in Morristown, NJ, USA. 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. In addition to Xadago® 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. www.newron.com.

Further Information

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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.

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