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Eisai Co., Ltd.
Meiji Seika Pharma Co., Ltd.

PRIMARY ENDPOINT MET IN PHASE II / III CLINICAL STUDY OF INVESTIGATIONAL PARKINSON'S DISEASE TREATMENT SAFINAMIDE IN JAPAN

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") and Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, CEO: Daikichiro Kobayashi, "Meiji") announced today that the primary endpoint was met in a Phase II/III clinical study on the investigational Parkinson's disease treatment ME2125 (safinamide mesylate, "safinamide") in patients with Parkinson's disease. Having received the results of the study, Meiji plans to submit a marketing authorization application for safinamide in Japan during 2018.

The study was a multicenter, double-blind, placebo-controlled, randomized, parallel group study to evaluate the efficacy and safety of two doses of safinamide (50 and 100 mg, once a day for 24 weeks) administered orally as add-on therapy in Japanese patients with Parkinson's disease with wearing-off phenomenon*1 who are currently receiving levodopa. The study was conducted by Meiji in Japan in accordance with the licensing agreement between the two companies. In this study, the primary endpoint was the change in mean daily "on" time*2 from baseline to 24 weeks of the treatment phase.

From the preliminary results of the study, the safinamide group (50 and 100 mg/day, respectively) demonstrated a statistically significant increase in "on" time compared to the placebo group. In addition, the four most commonly reported adverse events in the safinamide groups in the study were nasopharyngitis, dyskinesia, fall, and contusion.

Under the agreement signed between Eisai and Meiji in March 2017, Eisai obtained the exclusive rights to safinamide to market in Japan and to develop and market in Asia *3. Meiji will continue the clinical trials that it is currently conducting and submit a marketing authorization application for the drug in Japan. Meanwhile, Eisai will conduct clinical trials for seeking regulatory approval, and make the applications in Asia.

Through the development of safinamide, 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.

*1 Wearing off phenomenon: As the disease progresses, levodopa's duration of effect ("on" time) decreases, and Parkinson's disease symptoms return before the next dose
*2 On time: Period of time in which Parkinson's disease symptoms are suppressed due to the effect of levodopa
*3 South Korea, Taiwan, Brunei, Cambodia, Laos, Malaysia, the Philippines, Indonesia, Thailand, Vietnam, Myanmar, Singapore, Hong Kong, Macao

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<Notes to editors>

1. About safinamide mesylate (generic name, development code: ME2125)

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.[1,2]

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 develop, manufacture and commercialize the drug in Japan and Asia. Safinamide is marketed under the name “Xadago” in 13 countries in Europe and the United States.

2. About Parkinson’s Disease

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

According to Eisai’s internal estimates, there are approximately 300,000 patients suffering from Parkinson’s disease in Asia (excluding China and India). 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 2014.[3] The number of patients increasing due to the aging of the population.[4]

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.

3. 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/

4. About Meiji Seika Pharma Co., Ltd.

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] 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

[2] Schapira AH et al. Assessment of Safety and Efficacy of Safinamide as a Levodopa Adjunct in Patients With Parkinson Disease and Motor Fluctuations: A Randomized Clinical Trial. *JAMA Neurol*. 2017 Feb 1;74(2):216-224

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

[4] Japan Intractable Diseases Information Center http://www.nanbyou.or.jp/