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Eisai Co., Ltd.

EISAI TO TAKE OVER MANUFACTURING AND MARKETING APPROVAL FOR EQUFINA® 50MG TABLETS (SAFINAMIDE MESILATE) IN JAPAN FROM MEIJI SEIKA PHARMA

Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") announced today that it will take over by transfer the manufacturing and marketing approval of Parkinson's disease treatment Equfina® 50mg TABLETS (safinamide mesilate, "Equfina") in Japan from Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, "Meiji"), effective September 23, 2020.

In Japan, Meiji conducted clinical studies of Equfina and obtained its manufacturing and marketing approval in September 2019. Eisai has exclusively sold Equfina in Japan as a distributor. Based on the license agreement signed between Eisai and Meiji, Eisai will take over by transfer the manufacturing and marketing approval of Equfina from Meiji. Eisai, as the manufacturer and distributor of Equfina in Japan, will continue to provide information on the proper usage of Equfina.

Equfina, developed by Meiji in Japan, is a once-daily oral treatment for Parkinson's disease. It is a selective and reversible monoamine oxidase B (MAO-B) inhibitor that helps to maintain the density of endogenous dopamine and exogenous dopamine from levodopa-containing drugs in the brain (dopaminergic mechanism). In addition, Equfina blocks voltage-dependent sodium ion channels and inhibits glutamate release (non-dopaminergic mechanism). In the clinical studies conducted in Japan for Parkinson's disease patients under treatment with a drug containing levodopa, the extension of levodopa's duration of effect ("on" time) of one hour or more and improvement of motor functions were shown. Improvement effect on the wearing off phenomenon is expected.

Following the completion of the transfer, Eisai will continue to deliver Equfina, a new option for Parkinson's disease treatment in Japan to patients, thereby increasing the amount of time that they can freely engage in activities on their own initiative. Eisai will further contribute to improving the QOL of patients and enabling their families to create a vibrant daily life.

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[Notes to editors]

1. About Equfina (safinamide mesylate "safinamide")

Safinamide is a selective monoamine oxidase B (MAO-B) inhibitor that 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.

Safinamide was discovered and developed by Newron Pharmaceuticals S.p.A. (Headquarters: Milan, Italy, "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. Eisai has exclusive rights for marketing in Japan, as well as for development and marketing in Asia* based on a licensing agreement signed between Eisai and Meiji. Safinamide mesilate is marketed under the name "Xadago" in 15 countries in Europe, the United States and Australia, and under the name "Onstryv" in Canada.

* South Korea, Taiwan, Brunei, Cambodia, Laos, Malaysia, the Philippines, Indonesia, Thailand, Vietnam, Myanmar, Singapore, Hong Kong, and Macau

2. About Parkinson's Disease

Parkinson's disease is a neurodegenerative disease that causes motor impairment such as shaking in the limbs, muscular rigidity and shuffling gait, as well as non-motor impairment such as sensation impairment with pain, insomnia, and autonomic failure. It is caused by degeneration of the dopamine nervous system, which leads to a shortage of dopamine, a neurotransmitter in the brain. According to an estimate by the Japanese Society of Neurology, there are approximately 200,000 patients suffering from Parkinson's disease in Japan.[1] Also, approximately 3 million patients suffer from Parkinson's disease in Asia.[2] The number of patients is increasing due to aging of the population.[3] Levodopa is widely used to treat Parkinson's disease by replenishing the brain's supply of dopamine. However, as the disease progresses, the duration of effect of a drug containing levodopa ("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 a drug containing levodopa is administered.

3. 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 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 to contribute to the well-being of people worldwide.

For details, please visit its corporate website:

https://www.meiji.com/global/about-us/corporate-profile/meiji-seika-pharma/

[1] Japanese Society of Neurology. Treatment and Management Guideline 2018 for Parkinson's Disease

[2] E Ray Dorsey et al. Global, regional, and national burden of Parkinson's disease, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016 *Lancet Neurol.* 2018;17:939–53

[3] Japan Intractable Diseases Information Center: https://www.nanbyou.or.jp/