

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

Meiji Seika Pharma Co., Ltd. (Headquarters: Tokyo, CEO: Daikichiro Kobayashi, "Meiji") and Eisai Co., Ltd. (Headquarters: Tokyo, CEO: Haruo Naito, "Eisai") 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<sup>\*1</sup> 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<sup>\*2</sup> 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<sup>\*3</sup>. 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.

<sup>\*1</sup> 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

<sup>\*2</sup> On time: Period of time in which Parkinson's disease symptoms are suppressed due to the effect of levodopa

<sup>\*3</sup> South Korea, Taiwan, Brunei, Cambodia, Laos, Malaysia, the Philippines, Indonesia, Thailand, Vietnam, Myanmar, Singapore, Hong Kong, Macao