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# Eisai, Meiji receive approval for Parkinson's drug

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Eisai Co., Ltd. and Meiji Seika Pharma Co., Ltd. have announced the manufacturing and marketing approval in Japan for the indication of improvement of wearing-off phenomenon in patients with Parkinson's disease under treatment with a drug containing levodopa for Equfina® TABLETS (safinamide mesilate, "safinamide"), which was developed for use in the treatment of patients with Parkinson's disease was obtained. In Japan, Meiji holds the manufacturing and marketing approval for safinamide, and Eisai exclusively sells the safinamide.

This manufacturing and marketing approval is based on a double-blind, placebo-controlled Phase II/III study (study ME2125-3) to evaluate the efficacy and safety of safinamide as add-on therapy and an open label Phase III study (study ME2125-4) to evaluate the safety and efficacy of long-term administration of safinamide in Japanese patients with Parkinson's disease with wearing-off phenomena who are currently receiving levodopa, as well as global clinical trials.

In study ME2125-3, the change in mean daily "on" time from baseline to 24 weeks of the treatment phase, which is the primary endpoint, of treatment with safinamide 50 mg and 100 mg were statistically significant compared to placebo-controlled treatment. The most common adverse drug reactions (ADRs) (incidence 3% and higher) observed with patients with safinamide 50 mg and 100 mg were dyskinesia and visual hallucination. Also in study ME2125-4, with regard to the change in mean daily "on" time from baseline to 52 weeks of the treatment phase, the "on" time with long-term administration of safinamide was extended, and showed the continued effectiveness. The most common ADRs (incidence 3% and higher) observed with patients were dyskinesia, falls, and constipation.

By providing Equifina TABLETS as a new option for Parkinson's disease treatment, Eisai and Meiji will make further contributions to address the diverse needs of, and increase the benefits provided to, Parkinson's disease patients and their families.