[P01.061] Safinamide as an Add-On Therapy to a Stable Dose of a Single Dopamine Agonist: Results from a Randomized, Placebo-Controlled, 24-Week Multicenter Trial in Early Idiopathic Parkinson Disease (PD) Patients (MOTION Study)

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OBJECTIVE: To evaluate the efficacy and safety of two fixed doses of safinamide (50 and 100mg/day), compared to placebo, as add-on treatment to early PD patients receiving a stable dose of a single DA-agonist. **BACKGROUND:** Safinamide has previously demonstrated efficacy at doses of 50-100mg/day as add-on therapy to DA-agonist in early PD patients in placebo-controlled trials, and as add-on treatment to levodopa and other PD medications in fluctuating patients. **DESIGN / METHODS:** The MOTION study evaluated the efficacy of the two doses of safinamide compared to placebo on motor symptoms (primary endpoint:UPDRSIII improvement), activities of daily living (ADL), non-motor symptoms and quality of life in early PD patients on optimized doses of a single DA-agonist in a 24-week double-blind, placebo-controlled trial performed in North and South America, Europe, and India. Analyses were hierarchical; if the primary endpoint was not significant for the 100mg/day dose, subsequent endpoint analyses were considered exploratory. **RESULTS:** 607 (approximately 90%) out of 679 randomized patients completed the 24-week treatment period. Serious AEs were infrequent (<5%) and similar across treatments. Common AEs (≥5%) were arthralgia, dizziness, somnolence, headache, nausea, nasopharyngitis, back pain. In patients on monotherapy with a single DA-agonist (666 patients), safinamide 100mg/day significantly improved motor symptoms UPDRSIII (mean change), and PDQ-39 compared to placebo. There was borderline significant improvement in ADL for the 100mg/day as well as UPDRSIII (responders) for the 50mg/day group. **CONCLUSIONS:** Safinamide 100mg/day met the primary objective of significantly improving motor symptoms, quality of life, and borderline significantly ADL, compared to placebo as add-on to a single DA-agonist. These results confirm the efficacy and good tolerability profile of safinamide, already demonstrated in previous studies. Safinamide is a new treatment option for patients with early PD who show signs of loss of benefit on DA-agonist monotherapy. Supported by: Newron/MerckSerono.

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65th AAN Annual Meeting in San Diego, March 16–23, 2013

[P01.062] Safinamide Add on to L-Dopa: A Randomized, Placebo-Controlled, 24-Week Global Trial in Patients with Parkinson's Disease (PD) and Motor Fluctuations (SETTLE)

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OBJECTIVE: To evaluate the efficacy and safety of flexible doses of safinamide, α-aminoamide with both dopaminergic and nondopaminergic mechanism of action, 50-100 mg/day as add-on therapy to stable doses of levodopa and other PD medications, in PD patients with motor fluctuations. **BACKGROUND:** Safinamide has previously demonstrated efficacy as add on to dopamine agonist in non fluctuating patients, and as add on to levodopa and other PD medications in patients with motor fluctuations at fixed doses of 50 and 100mg/day in 6 months treatment trials. **DESIGN / METHODS:** The SETTLE study evaluated effects of safinamide on motor fluctuations (primary efficacy endpoint: increase in "ON" time), UPDRS scores, QoL and non-motor symptoms in patients with PD on optimized anti-parkinsonian treatment over 24 weeks in a double-blind, placebo-controlled trial performed in North America, Europe, and Asia-Pacific regions. Analysis was hierarchical; if the primary endpoint was not significant, subsequent endpoint analyses were considered exploratory. **RESULTS:** 484 of 549 randomized patients completed 24 weeks' treatment. Safinamide 50-100 mg/day significantly improved ON time (without worsening troublesome dyskinesia), OFF time, UPDRS III, CGI-S, CGI-C, PDQ-39 and OFF time following the first morning levodopa dose (i.e. latency to ON) compared to placebo. The discontinuation rate, and serious AEs were similar across treatments. The most frequent AEs (≥ 5% in one group or more) were back pain, dyskinesia, fall, headache, nausea, and urinary tract infection. **CONCLUSIONS:** Safinamide 50-100 mg/day met the primary efficacy objective of significantly improving ON time without any increase in troublesome dyskinesia, and there was improvement in multiple secondary efficacy measures. These results confirm the efficacy and good tolerability demonstrated previously in Study 016 at daily doses of 50mg and 100 mg. Supported by: Newron/Merck Serono.
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