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Pilot study on the effect of combined treatment with safinamide and opicapone in fluctuating PD patients

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Introduction: Fluctuations and dyskinesia are frequent complications in Parkinson's disease (PD) patients treated with levodopa. Monoamine-oxidase-B (MAO-B) and catechol-O-methyl-transferase (COMT) inhibitors increase levodopa and dopamine availability through different mechanisms, and display therapeutic efficacy on fluctuations in PD patients, as well as similar side-effects. Based on the different mechanism of action of these drugs, the question raises of whether combining MAO-B and COMT inhibition may provide further benefit to fluctuating PD patients.

Objective: Here we preliminarily investigated the tolerability, safety and efficacy of add-on with safinamide 100 mg (SF) and opicapone 50 mg (OPC) in fluctuating PD subjects.

Methods: Seven PD patients displaying re-occurrence of fluctuations while under add-on therapy with either SF or OPC underwent combined treatment with the two drugs. SF was administered in the morning and OPC in the evening. The remaining antiparkinsonian therapy was unmodified. Outcome measures included MDS-UPDRS-III, NMSS and WOK-19 scores.

Results: After 4 months of add-on with SF+OPC, there was marked reduction of WOK-19 score, together with significant improvements of both MDS-UPDRS-III at the end of levodopa dose and NMSS score. Sleep was the most significantly improved non motor domain. Patients did not report clinically relevant side effects, in particular there was no evidence of development/worsening of dyskinesia.

Conclusions: These preliminary results show the tolerability, safety and efficacy of combining SF and OPC in fluctuating PD patients. The effects on sleep pattern and quality suggest that such potentiation of dopamine replacement therapy may provide particular benefit during night-time and akinesia at awakening. Furthermore, the antiglutamatergic mechanism of high dose SF may be useful for anti-dyskinetic effects. If confirmed on larger studies, add-on with SF+OPC may provide a convenient strategy for second line treatment of motor and nonmotor complications of PD.