Changes to Levodopa Daily Dose in Parkinson’s Disease (PD) Patients with Dyskinesia While on GocovriTM (Amantadine) Extended Release Capsules: a Two-Year Phase 3 Open Label Study Analysis
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Objective:
Characterize the safety and efficacy of 274 mg Gocovri in patients who adjusted their levodopa daily dose prior to completion of the two-year open label study.

Background: Patients with OFF periods may not be able to increase levodopa due to dyskinesia, while dyskinetic patients may not be able to lower levodopa due to OFF time. Gocovri is the only Parkinson’s disease (PD) medicine shown to decrease dyskinesia in PD patients treated with levodopa, while also reducing OFF time. Safety and efficacy of Gocovri (274 mg) in PD patients was established in two pivotal phase 3 studies (EASE LID and EASE LID 3), and an open label study (EASE LID 2).

Design/Methods:
Unlike the pivotal phase 3 trials, PD medications (including levodopa) could be adjusted in this study. We evaluated the safety and efficacy of Gocovri in patients who increased, maintained, or decreased their daily levodopa dose upon completion of EASE LID 2.

Results:
Of the 223 patients enrolled, 129 (58%) completed two years of treatment. Baseline characteristics included a mean PD duration of 11.8 years, a mean levodopa daily dose of 695 mg, and a mean MDS-UPDRS, Part IV score of approximately 9.0. Of these patients, 39 (30%) increased, 69 (54%) maintained, and 21 (16%) decreased their levodopa daily dose from baseline. The mean change was +298 mg (range: 50 to 840) for those who increased and -198 mg (range: -25 to -700) among those who decreased. The observed mean change from Baseline to Week 100 in MDS-UPDRS, Part IV was -1.7, -2.6, and -1.8, in those who increased, maintained, or decreased their levodopa daily dose, respectively. Adverse drug reactions in this population were consistent across all subgroups.

Conclusions: These open label data suggest long-term adjunctive treatment with Gocovri may enable the levodopa regimen to be optimized in PD patients experiencing motor complications.