Amantadine ER (GOCOVRI®) : Adis Evaluation

Clinical Considerations

- Delayed-release, extended-release (DR/ER) oral formulation administered once daily at bedtime
- Significantly improves dyskinesia and OFF time relative to placebo
- Significantly increases ON time without troublesome dyskinesia relative to placebo
- Durable clinical benefits with long-term treatment
- Generally well tolerated

Plain Language Summary

Background and rationale

- Parkinson's disease (PD), a common neurodegenerative disease, is associated with motor and non-motor symptoms and thus exerts a considerable burden on the health system
- Levodopa is considered the gold standard treatment for PD; however, prolonged use is associated with reduced efficacy in the setting of more advanced disease and the emergence of motor complications of dyskinesia and OFF episodes Management of these motor complications often involves the trade-off between treating one or the other
- Amantadine extended release (ER) capsules (GOCOVRI®), administered once daily at bedtime, are the first to be approved in the USA to treat both dyskinesia and OFF episodes in PD

Clinical findings

- Evidence for the efficacy of amantadine ER has been demonstrated in two randomized, placebo-controlled phase III trials in PD patients with levodopa-induced dyskinesia (LID), where it reduced dyskinesia and OFF time and increased ON time without troublesome dyskinesia, relative to placebo
- Benefits with amantadine ER were durable over long-term treatment
- Amantadine ER is generally well tolerated in patients with LID, with no new safety concerns identified during longer-term use

Conclusion

Given its efficacy and tolerability profile, amantadine ER is an important treatment option for the management of LID and OFF episodes in PD patients