Efficacy and Safety of Once-Daily Opicapone 50 mg in Patients with Parkinson’s Disease and Motor Fluctuations: Pooled Analysis of Two Randomized, Double-Blind, Placebo-Controlled Studies

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INTRODUCTION

Lewy body pathology is the excellent feature for managing the signs and symptoms of Parkinson’s disease (PD), including levodopa–

Introduction of uncontrolled fluctuations and motor fluctuations (OFF periods) as major clinical concerns.

Close to 20% of patients with PD experience motor fluctuations, which are challenging to manage and affect daily life. Despite the existence of OFF periods, significant or qualitative treatment-by-subgroup interactions were observed.

In the pooled Full Analysis Set (FAS), changes from baseline in absolute OFF-time were analyzed by study visit (Weeks 1, 2/3, 6/7, and 10/11), and the end of DB treatment (Week 14/15).

The change from baseline in absolute OFF-time at Week 14/15 was least squares mean changes (± standard error) of -2.22 (±0.17) hours for opicapone 50 mg (p < 0.006), compared with -0.9 (±0.4) hours for placebo (p = 0.001).

The overall survival of Table 14 was higher with opicapone 50 mg compared with placebo, but this relationship is not clear in the placebo arm.

The study endpoints were also evaluated in a sensitivity analysis in the post hoc subgroup analysis, with no statistically significant differences observed.

The study was randomized, double-blind, placebo-controlled, and included patients with Parkinson’s disease and motor fluctuations who were treated with opicapone 50 mg or placebo for 14 weeks.

The most common safety endpoints were dry mouth, constipation, and urinary incontinence, which were observed in ≤5% of participants in any treatment group.

One death in the placebo group due to pneumonia was reported in >5% of participants in any treatment arm.

Any serious TEAE occurred in ≤5% of participants in any treatment arm.

In BIPARK-1, participants were randomized (1:1:1:1:1) to DB treatment with opicapone (5, 25, or 50 mg), entacapone (200 mg), or placebo, and the placebo arm was discontinued after Week 6.

The most common adverse events were dry mouth, constipation, and urinary incontinence, which were observed in ≤5% of participants in any treatment group.

Conclusions:

In the post hoc subgroup analysis, no statistically significant differences were observed between opicapone 50 mg and placebo in terms of any serious AD, but significant differences were observed in terms of the incidence of serious AD in the placebo arm.

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