Table 2. ORs From Final Regression Models

Parameter	MADRS Model		EWB Model	
	OR (95% CI)	*P* Value	OR (95% CI)	*P* Value
ESL 1200 mg vs PBO	2.68 (1.94 to 3.69)	< .001	2.64 (1.92 to 3.64)	< .001
ESL 800 mg vs PBO	1.89 (1.37 to 2.62)	< .001	1.89 (1.37 to 2.61)	< .001

ESL, eslicarbazepine acetate; EWB, Emotional Well-Being subscale; MADRS, Montgomery-Åsberg Depression Rating Scale; PBO, placebo.

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Levodopa-Carbidopa Intestinal Gel Shows Promise in Advanced Parkinson Disease

Written by Maria Vinall

Interim data from an ongoing phase 3b trial, presented in a poster by Jordan Dubow, MD, AbbVie, Inc., North Chicago, Illinois, USA, indicated that treatment with levodopa-carbidopa intestinal gel (LCIG) significantly improved nonmotor symptoms (NMSs) in patients with advanced Parkinson disease (PD).

NMSs play an important role, clearly affecting health-related quality of life (HRQOL) of patients with PD. LCIG (carbidopa-levodopa enteral suspension) is an effective treatment option for motor fluctuations in advanced refractory PD [Olanow CW et al. *Lancet Neurol.* 2014]. Open-label studies have shown that LCIG is associated with significant improvements in NMSs and HRQOL in patients with advanced PD [Fasano A et al. *Eur Rev Med Pharmacol Sci.* 2012; Reddy P et al. *Clin Neuropharmacol.* 2012].

This phase 3b, open-label, multicenter study [NCT01736176] included patients aged ≥30 years with levodopa-responsive idiopathic PD and severe motor fluctuations with ≥3 hours of "off" time/day (despite individually optimized therapy). After conversion to oral levodopa-carbidopa, all patients underwent a percutaneous endoscopic gastrostomy-jejunostomy placement procedure. The study included an initial 12-week LCIG treatment period and a 48-week long-term treatment period. The primary end point was the change in NMSs from baseline to week 12 as measured by the Non-Motor Symptoms Scale (NMSS) total score. Secondary end points included the change from baseline to week 12 in the 9 NMSS domains. Adverse events (AEs) were recorded. Interim analysis was completed for the first 17 of 36 participants.

Patients had a mean age of 64 years (range, 45-76), 65% were men, and 94% were white. Mean exposure to LCIG was 180 days (range, 5-368 days). Fourteen of 17 patients had a reduction in NMSS total score between baseline and final evaluation; the mean reduction was 38.3% (–20.7; $P = .001$).

Significant decreases were noted in 3 of the 9 NMSS domains: sleep/fatigue (–6.7; $P = .008$), sexual function (–2.5; $P = .011$), and miscellaneous (–4.9; $P = .002$).

At least 1 treatment-emergent AE was reported for 16 patients, and 2 patients discontinued due to AEs. The most frequently reported AEs were procedural pain (65%) and anxiety (24%). Serious AEs were reported for 2 patients; neither was considered related to LCIG.

This study provides additional evidence that LCIG can be a safe and effective treatment for NMSs in patients with advanced PD.

Brivaracetam Reduces Seizure Frequency in Patients With Partial-Onset Seizures

Written by Maria Vinall

Pavel Klein, MD, Mid-Atlantic Epilepsy and Sleep Center, Bethesda, Maryland, USA, presented the results of a phase 3 trial [NCT01261325] showing that adjunctive treatment with brivaracetam is associated with a significant reduction in the frequency of partial-onset seizures (POS) and improved response.

Brivaracetam is a selective high-affinity synaptic vesicle protein 2A ligand in clinical development for the treatment of epilepsy. The objective of this multicountry phase 3 study was to evaluate the efficacy, safety, and tolerability of brivaracetam compared with placebo as an adjunctive therapy in adult patients with focal epilepsy. Patients enrolled in this study had POS not fully controlled, despite treatment with 1 or 2 concomitant antiepileptic drugs. The study consisted of an 8-week baseline observational period and a 12-week treatment period, after which patients could undergo a 4-week down titration or enter into an open-label follow-up study. The co–primary efficacy outcomes were percentage reduction over placebo in 28-day adjusted seizure frequency and ≥50% responder rate based on percentage reduction in seizure frequency from baseline to the treatment period.

Patients aged ≥16 to 80 years with refractory POS who experienced ≥8 POS during the 8-week baseline period and ≥2 POS per month, with or without secondary generalization, during the 3 months prior to screening were recruited. Eligible patients were randomized 1:1:1 to placebo or brivaracetam 100 or 200 mg/d BID. During the 12 weeks of treatment, the rate of discontinuation was low and mostly due to adverse events (AEs; 3.8% in the placebo group and 8.3% and 6.8% among patients in the