SUPPLEMENTARY MATERIAL

Improvement in Motor Consistency and Stability With Foslevodopa/Foscarbidopa in Parkinson's Disease: Post Hoc Analysis of Two Phase 3 Clinical Trials

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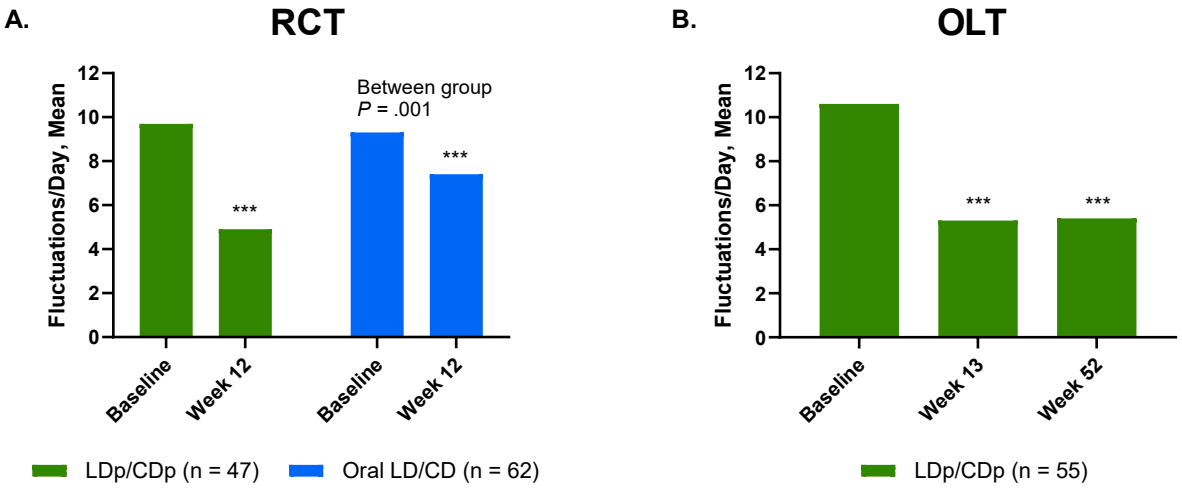
Supplemental Table 1. Regression model estimates of categorical number of motor fluctuations during the 16-hour waking day for participants receiving LDp/CDp and oral LD/CD in the 12-week RCT and 52-week OLT.

RCT	LDp/CDp		Oral IR LD/CD	
Type of fluctuations	Baseline n (%) n = 48	Week 12 Estimate % (95% CI)	Baseline n (%) n = 62	Week 12 Estimate % (95% CI)
3-state[a]				
≤3	3 (6.3)	53.0 (37.7, 68.2)	5 (8.1)	26.0 (15.2, 36.8)**
>3 to ≤6	18 (37.5)	31.0 (17.6, 44.4)	18 (29.0)	36.2 (24.5, 47.8)
>6 to ≤9	16 (33.3)	14.3 (4.2, 24.5)	25 (40.3)	24.6 (14.5, 34.7)
>9	11 (22.9)	1.9 (−3.0, 6.7)	14 (22.6)	13.1 (5.2, 21.0)*
5-state[b]				
≤3	0 (0.0)	34.6 (21.3, 47.8)	1 (1.6)	15.7 (6.6, 24.8)*
>3 to ≤6	6 (12.5)	26.0 (12.6, 39.3)	9 (14.5)	19.0 (9.5, 28.6)
>6 to ≤9	16 (33.3)	30.9 (17.1, 44.6)	24 (38.7)	36.3 (24.2, 48.4)
>9	26 (54.2)	7.6 (−1.1, 16.3)	28 (45.2)	29.7 (19.2, 40.3)**

OLT	LDp/CDp		
Type of fluctuations	Baseline n (%) n = 132	Week 13 Estimate (95% CI)	Week 52 Estimate (95% CI)
3-state[a]			
≤3	17 (12.9)	59.5 (49.1, 69.8)	66.6 (55.4, 77.8)
>3 to ≤6	35 (26.5)	26.4 (17.0, 35.9)	17.6 (7.9, 27.2)
>6 to ≤9	45 (34.1)	8.0 (2.3, 13.7)	9.9 (2.2, 17.5)
>9	35 (26.5)	6.1 (1.1, 11.1)	6.0 (0.5, 11.6)
5-state[b]			
≤3	3 (2.3)	32.8 (22.6, 43.0)	30.8 (18.6, 43.0)
>3 to ≤6	14 (10.6)	34.6 (24.0, 45.2)	39.7 (26.7, 52.8)
>6 to ≤9	38 (28.8)	21.8 (13.0, 30.7)	16.0 (6.7, 25.2)
>9	77 (58.3)	11.0 (4.0, 17.9)	12.9 (4.7, 21.1)

*P < .05 for treatment difference of LDp/CDp minus oral IR LD/CD.
**P < .01 for treatment difference of LDp/CDp minus oral IR LD/CD.
[a]Three-state fluctuations were assessed by the number of transitions between the following motor states throughout a 16-hour waking day: “Off,” good “On”, and “ON” with troublesome dyskinesia.
[b]Five-state fluctuations evaluated the number of transitions between the following states: “Off,” “On” with troublesome dyskinesia, “On” without dyskinesia, “On” with non-troublesome dyskinesia, and asleep. One participant in the LDp/CDp group of the RCT was not included due to missing data at week 12.
IR, immediate release; LD/CD, oral levodopa/carbidopa; LDp/CDp, foslevodopa/foscarbidopa; OLT, open-label trial; RCT, randomized controlled trial.

Supplemental Figure 1. Number of 5-state fluctuations per day during 16-hour waking day in the (A) RCT and (B) OLT. Good “On” time, “On” time without troublesome dyskinesia and “On” time with non-troublesome dyskinesia; LD/CD, levodopa/carbidopa; LDp/CDp, foslevodopa/foscarbidopa; OLT, open-label trial; RCT, randomized controlled trial. Data are not adjusted for covariates. Five-state fluctuations evaluated the number of transitions between the following states: “Off,” “On” with troublesome dyskinesia, “On” without dyskinesia, “On” with non-troublesome dyskinesia, and asleep. One participant in the LDp/CDp group of the RCT was not included due to missing data at week 12. ***Nominal *P* < .001 vs baseline.



Supplemental Figure 2. Number of 5-state fluctuations per day during 4-hour blocks of the 16-hour waking day in the (A) RCT and (B) OLT. Good "On" time, "On" time without troublesome dyskinesia and "On" time with non-troublesome dyskinesia; LD/CD, levodopa/carbidopa; LDp/CDp, foslevodopa/foscarbidopa; OLT, open-label trial; RCT, randomized controlled trial. Data are not adjusted for covariates. The waking day time periods were defined as morning, 0–4 hours after waking; midday, 4–8 hours after waking; afternoon, 8–12 hours after waking; evening, 12–16 hours after waking. Five-state fluctuations evaluated the number of transitions between the following states: "Off," "On" with troublesome dyskinesia, "On" without dyskinesia, "On" with non-troublesome dyskinesia, and asleep. One participant in the LDp/CDp group of the RCT was not included due to missing data at week 12. ***Nominal *P* < .001 vs baseline.