

Real-World Safety and Effectiveness of 24-Hour Foslevodopa/Foscarbidopa in Parkinson's Disease: ROSSINI Study 6-Month Interim Results

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Supplementary Materials

Figure S1

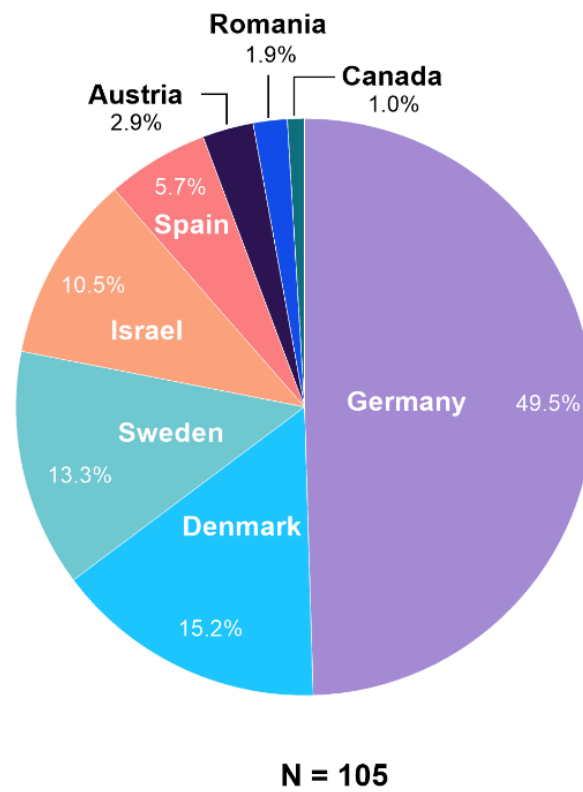


Figure S1. Proportion of enrolled patients per country (safety analysis set).

Figure S2

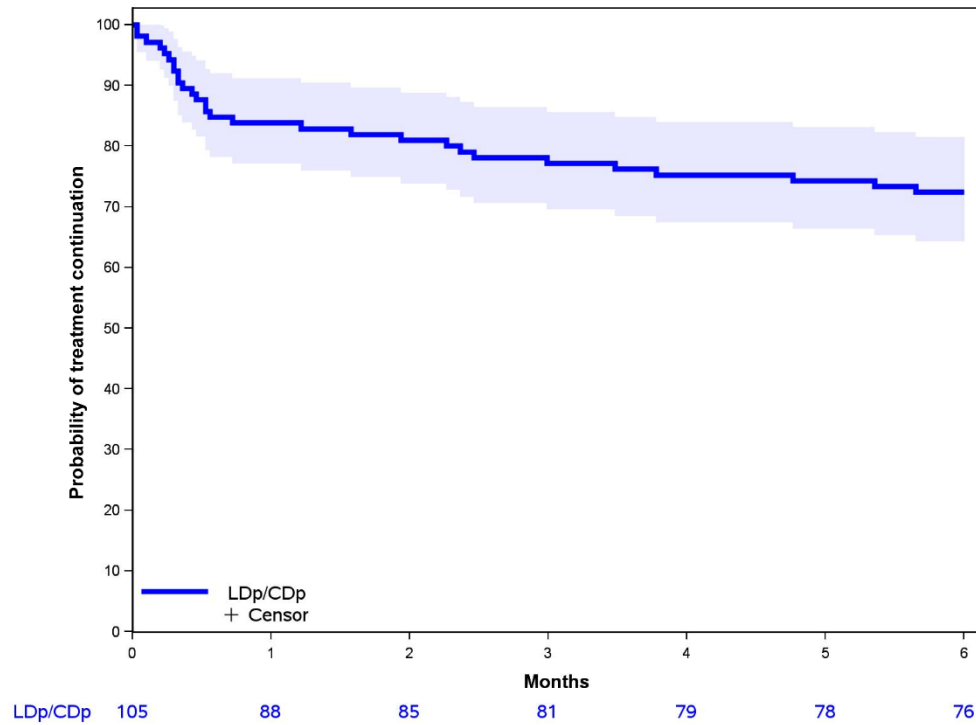


Figure S2. Kaplan-Meier curve for treatment discontinuations (safety analysis set).

Figure S3

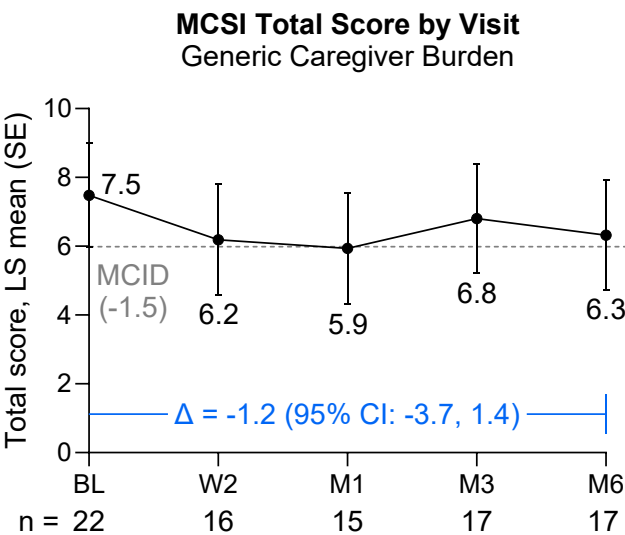


Figure S3. LS means by visit for caregiver burden as measured by MCSI scores (full analysis set). ^ΔValues represent LS mean change from baseline to M6, estimated from a mixed model for repeated measures adjusted for country. Abbreviations: BL, baseline; MCSI, Modified Caregiver Strain Index; M, month; W, week; MCID, minimal clinically important difference; SE, standard error. MCID reference: MCSI (-1.5 to -2.3) [41].

Table S1. Significant improvements in endpoint subdomains at month 6 from baseline (full analysis set).

Outcome	Significantly Improved Subdomain by Preferred Term^a
KPPS score	Chronic pain, fluctuation-related pain, nocturnal pain, discoloration
GIDS-PD score	Bowel irritability, upper GI symptoms
PDSS-2 score	Motor symptoms at night, PD symptoms at night, disturbed sleep
PDQ-39 score	Mobility, emotional well-being, bodily discomfort
^a Nonsignificant score changes were evaluated in the following subdomains for each outcome: KPPS, musculoskeletal pain, oro-facial pain, radicular pain; GIDS-PD, constipation; PDQ-39, activities of daily living, stigma, social support, cognition, and communication. Abbreviations: GI, gastrointestinal; GIDS-PD, Gastrointestinal Dysfunction Scale in Parkinson's Disease; KPPS, King's PD Pain Scale; PDSS-2, Parkinson's Disease Sleep Scale-2; PDQ-39, 39-item Parkinson's Disease Questionnaire.	

Table S2. Summary and change from baseline^a of body weight with LDp/CDp in cohort A.

	Baseline	Week 2	Month 1	Month 3	Month 6
Body weight, kg, mean (SD)	73.1 (16.3)	74.7 (15.8)	76.2 (15.5)	73.5 (14.5)	73.8 (13.8)
<i>n</i>	91	82	58	68	65
CFB, mean (SD)	–	0.5 (4.7)	1.0 (6.3)	0.0 (6.1)	-0.5 (7.7)
^a Only includes subjects with nonmissing baseline and at least one post baseline value. Abbreviations: CFB, change from baseline.					