

Supplemental Online Content

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This supplemental material has been provided by the authors to give readers additional information about their work.

eTable 1. Demographics and Study Entry Characteristics

Demographic/characteristic	Total (n=630)	Not randomized (n=124)	IPX203 (n=256)	IR CD-LD (n=250)
Age (y), mean (SD)	66.5 (8.95)	67.3 (9)	66.1 (9.02)	66.5 (8.85)
Gender, males, n (%)	396 (62.9)	60 (48.4%)	159 (62.1%)	177 (70.8%)
Gender, females, n (%)	234 (37.1)	64 (51.6)	97 (37.9)	73 (29.2)
Age of onset of PD (y), mean (SD)	58 (9.42)	58 (9.72)	57.7 (9.13)	58.3 (9.60)
Hoehn and Yahr 2/3/4, %	90.5	90.3	89.4	91.6
Screening MoCA score, mean (SD)	27.1 (1.81)	26.8 (1.87)	27.3 (1.80)	27.2 (1.78)
MDS-UPDRS Part III (On), mean (SD)	24.7 (15.66)	24.1 (15.34)	24.7 (15.96)	24.9 (15.56)
MDS-UPDRS Part III (Off), mean (SD)	45.2 (14.33)	43.4 (15.47)	45.5 (13.96)	45.6 (14.11)
“Off” Time (h), mean (SD)	6.13 (2.21)	6.24 (2.36)	6.12 (2.16)	6.08 (2.18)
“Good On” time (h), mean (SD)	9.56 (2.27)	9.55 (2.46)	9.52 (2.21)	9.60 (2.34)
Total daily LD, mean (SD)	797.8 (335.30)	836.9 (338.93)	792.3 (329.10)	784.1 (339.64)
Total daily IR LD, mean (SD)	754.7 (322.87)	791.7 (321.01)	746 (320.82)	745.2 (325.84)

Abbreviations: PD, Parkinson's Disease; MoCA, MoCA, Montreal Cognitive Assessment; MDS-UPDRS, Movement Disorders Society-Unified Parkinson's Disease Rating Scale; LD, levodopa; IR CD-LD, immediate-release carbidopa-levodopa.

eTable 2: Data Summary of Efficacy Endpoints

Endpoints	IPX203 (N=249)	IR CD-LD (N=246)	Difference (IPX203 vs. IR CD-LD)	p value
Primary endpoint				
Change from baseline in “Good on” time, LS mean	-0.5	-1.03	0.53	0.02 ^a
Key secondary endpoints				
Change from baseline in “Off” time, LS mean	0.38	0.86	-0.48	0.03 ^a
Patients self-rated “Much Improved” or “Very Much Improved” on PGI-C, % ^c	29.7	18.8	10.9	0.002 ^b
Change from baseline in MDS-UPDRS Part III score, LS mean ^c	0.8	0.8	0	0.96 ^a
Change from baseline in sum of MDS-UPDRS Part II and III scores, LS mean ^c	1.7	1.8	0	0.97 ^a
Post-hoc analysis				
“Good on” time (h) per dose, LS mean	3.76	2.21	1.55	<0.0001 ^a

Abbreviations: IR CD-LD, immediate-release carbidopa-levodopa; LS, least square; MDS-UPDRS, Movement Disorders Society- Unified Parkinson’s Disease Rating Scale; PGI-C, Patient Global Impression of Change.

^a p value for the hypothesis of equal LS means.

^b p value from the Cochran-Mantel-Haenszel test stratified by pooled center comparing the proportion of much or very much improved patients between the treatment groups.

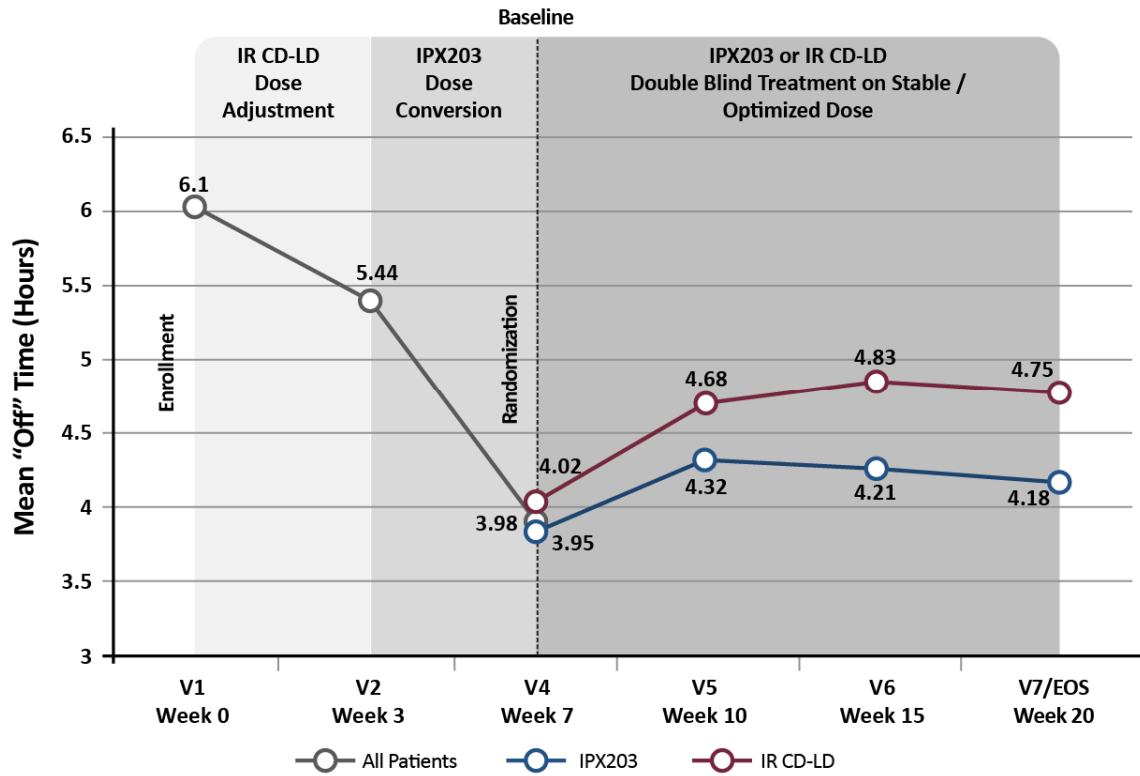
^c IPX203, N=256; IR CD-LD, N=250.

eTable 3: Levodopa Dosages and Dosing Frequencies in the Double-Blind Period, Randomized Analysis Set

Characteristic Statistic	IR CD-LD (N=250)	IPX203 (N=256)
Total daily dose of LD (mg)		
N	250	256
Mean (SD)	856.94 (378.68)	1488.05 (592.78)
Median (min, max)	800 (400, 2100)	1400 (420, 3360)
Daily dosing frequency (times/day)		
N	250	256
Mean (SD)	5.01 (1.19)	3.04 (0.40)
Median (min, max)	5 (3, 10)	3 (2, 4)

Abbreviations: IR CD-LD, immediate-release carbidopa-levodopa; LD, levodopa.

eFigure 1: Change from Baseline in “Off” Time, mITT Analysis Set



Abbreviations: EOS, end of study; IR CD-LD, immediate-release carbidopa-levodopa; mITT, modified intent-to-treat; V, Visit.