

Supplementary Table 2. Changes from baseline to week 24 in secondary outcomes

Outcome measure	Asian patients (n = 173)		Caucasian patients (n = 371)	
	Placebo (n = 85)	Safinamide (n = 88)	Placebo (n = 188)	Safinamide (n = 183)
DRS score				
Mean at baseline (SE)	2.20 (0.30)	2.61 (0.37)	2.74 (0.23)	2.89 (0.26)
LS mean (SE)	-0.10 (0.65)	0.20 (0.61)	-0.32 (0.18)	-0.12 (0.18)
LS difference vs. placebo (95% CI)	0.30 (-0.31, 0.90)		0.20 (-0.27, 0.67)	
p-value	0.3309 (NS)		0.4117 (NS)	
DRS score by subgroup				
DRS score at baseline > 0	n = 51	n = 53	n = 119	n = 114
Mean at baseline (SE)	3.67 (0.39)	4.34 (0.48)	4.33 (0.28)	4.63 (0.32)
LS mean change from baseline (SE)	-1.01 (1.00)	-0.63 (0.93)	-0.88 (0.26)	-0.58 (0.26)
LS difference vs. placebo (95% CI)	0.37 (-0.52, 1.27)		0.30 (-0.38, 0.99)	
p-value	0.4103 (NS)		0.3843 (NS)	
DRS score at baseline = 0	n = 34	n = 35	n = 69	n = 69
Mean at baseline (SE)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
LS mean change from baseline (SE)	1.07 (0.64)	1.37 (0.64)	0.55 (0.20)	0.66 (0.21)
LS difference vs. placebo (95% CI)	0.29 (-0.34, 0.93)		0.11 (-0.40, 0.61)	
p-value	0.3622 (NS)		0.6747 (NS)	
OFF-time after morning levodopa, hr				
Mean at baseline (SE)	0.94 (0.07)	0.91 (0.06)	0.82 (0.05)	0.79 (0.04)
LS mean change from baseline (SE)	-0.18 (0.19)	-0.40 (0.18)	-0.10 (0.05)	-0.26 (0.05)
LS difference vs. placebo (95% CI)	-0.22 (-0.40, -0.04)		-0.16 (-0.28, -0.04)	
p-value	0.0144		0.0105	
CGI-C rating				
Mean at baseline (SE)	NA	NA	NA	NA
LS mean (SE)	4.10 (0.33)	3.75 (0.31)	3.84 (0.08)	3.36 (0.09)
LS difference vs. placebo (95% CI)	-0.35 (-0.66, -0.04)		-0.48 (-0.70, -0.26)	
p-value	0.0254		< 0.0001	
CGI-S rating				
Mean at baseline (SE)	3.82 (0.06)	3.77 (0.07)	4.14 (0.05)	4.04 (0.06)
LS mean (SE)	-0.22 (0.21)	-0.40 (0.20)	-0.07 (0.05)	-0.17 (0.05)
LS difference vs. placebo (95% CI)	-0.18 (-0.37, 0.01)		-0.10 (-0.22, 0.03)	
p-value	0.0699 (NS)		0.1302 (NS)	
PGI-C rating				
Mean at baseline (SE)	NA	NA	NA	NA
LS mean change from baseline (SE)	3.68 (0.30)	3.28 (0.29)	3.70 (0.09)	3.34 (0.09)
LS difference vs. placebo (95% CI)	-0.40 (-0.68, -0.11)		-0.36 (-0.58, -0.14)	
p-value	0.0064		0.0014	
UPDRS part II (ON phase) total score				
Mean at baseline (SE)	8.25 (0.57)	8.00 (0.54)	11.38 (0.47)	10.88 (0.41)
LS mean changes from baseline (SE)	-0.09 (1.08)	-0.52 (1.02)	-0.95 (0.28)	-1.44 (0.29)
LS difference vs. placebo (95% CI)	-0.43 (-1.43, 0.57)		-0.48 (-1.22, 0.25)	
p-value	0.4009 (NS)		0.1969 (NS)	
UPDRS Part IV (items 32–34)				
Mean at baseline (SE)	1.56 (0.20)	1.55 (0.21)	2.06 (0.15)	2.07 (0.14)
LS mean (SE)	1.10 (0.47)	1.25 (0.45)	-0.38 (0.11)	-0.10 (0.11)
LS difference vs. placebo (95% CI)	0.16 (-0.28, 0.59)		0.28 (-0.01, 0.58)	
p-value	0.4786 (NS)		0.0575 (NS)	
UPDRS Part IV (items 32–35)				
Mean at baseline (SE)	1.87 (0.22)	1.86 (0.23)	2.43 (0.16)	2.35 (0.16)
LS mean change from baseline (SE)	0.87 (0.48)	1.14 (0.46)	-0.37 (0.12)	-0.13 (0.12)
LS difference vs. placebo (95% CI)	0.27 (-0.18, 0.72)		0.24 (-0.07, 0.55)	
p-value	0.2398 (NS)		0.1290 (NS)	
ESS				
Mean at baseline (SE)	4.91 (0.39)	5.52 (0.42)	6.95 (0.33)	7.03 (0.31)
LS mean change from baseline (SE)	0.80 (1.16)	0.69 (1.12)	-0.16 (0.25)	-0.36 (0.25)
LS difference vs. placebo (95% CI)	-0.11 (-1.00, 0.78)		-0.20 (-0.84, 0.44)	
p-value	0.8087 (NS)		0.5325 (NS)	
QUIP				
Mean at baseline (SE)	1.44 (0.35)	1.66 (0.42)	0.77 (0.15)	0.79 (0.14)
LS mean change from baseline (SE)	-0.32 (0.82)	-0.50 (0.77)	0.23 (0.18)	0.15 (0.18)
LS difference vs. placebo (95% CI)	-0.18 (-0.97, 0.61)		-0.08 (-0.53, 0.38)	
p-value	0.6479 (NS)		0.7341 (NS)	
EQ-5D index score				
Mean (SE) at baseline	0.66 (0.02)	0.67 (0.02)	0.68 (0.02)	0.69 (0.01)
LS mean changes from baseline (SE)	0.02 (0.05)	0.07 (0.04)	-0.04 (0.01)	0.02 (0.01)
LS difference vs. placebo (95% CI)	0.05 (0.01, 0.09)		0.06 (0.03, 0.10)	
p-value	0.0184		0.0010	

CI, confidence interval; CGI-C, Clinical Global Impression – Change; CGI-S, Clinical Global Impression – Severity; DRS, Dyskinesia Rating Scale; ESS, Epworth Sleepiness Scale; EQ-5D, EuroQoL Five Dimensions; LS, least squares; NA, not applicable; NS, not significant; PGI-C, Patient Global Impression – Change; QUIP, Questionnaire for Impulsive-Compulsive Disorders in Parkinson's Disease; SE, standard error; UPDRS, Unified Parkinson's Disease Rating Scale.