表 2.7.3.6-20　PANSS 5 因子モデル別合計スコア変化量　Cognitive Disorders
（20 試験：二重盲検治療期、MMRM、実施国別）

mITT Population

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
	Number of subjects analysed	51	55	56
Baseline	Mean (SD)	16.7 (3.69)	16.7 (4.11)	17.4 (3.88)
Week 1	Change from Baseline			
	Estimate (SE)	-0.7 (0.24)	-0.4 (0.23)	-1.1 (0.23)
	95% CI	(-1.2, -0.2)	(-0.8, 0.1)	(-1.6, -0.7)
	Treatment Difference			
	Estimate (SE)		0.3 (0.33)	-0.4 (0.33)
	95% CI		(-0.3, 1.0)	(-1.1, 0.2)
	p-value		0.304	0.177
Week 2	Change from Baseline			
	Estimate (SE)	-1.1 (0.35)	-0.7 (0.33)	-1.6 (0.33)
	95% CI	(-1.8, -0.4)	(-1.3, 0.0)	(-2.3, -1.0)
	Treatment Difference			
	Estimate (SE)		0.4 (0.48)	-0.5 (0.47)
	95% CI		(-0.5, 1.4)	(-1.5, 0.4)
	p-value		0.372	0.280
Week 4	Change from Baseline			
	Estimate (SE)	-1.1 (0.44)	-1.3 (0.42)	-2.5 (0.40)
	95% CI	(-1.9, -0.2)	(-2.1, -0.5)	(-3.3, -1.7)
	Treatment Difference			
	Estimate (SE)		-0.2 (0.60)	-1.4 (0.59)
	95% CI		(-1.4, 1.0)	(-2.6, -0.2)
	p-value		0.718	0.019
Week 6	Change from Baseline			
	Estimate (SE)	-1.0 (0.52)	-1.0 (0.49)	-2.8 (0.47)
	95% CI	(-2.0, 0.1)	(-2.0, -0.1)	(-3.7, -1.8)
	Treatment Difference			
	Estimate (SE)		-0.1 (0.71)	-1.8 (0.70)
	95% CI		(-1.5, 1.3)	(-3.2, -0.4)
	p-value		0.906	0.011

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
	Effect size		0.025	0.537

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
	Number of subjects analysed	9	9	10
Baseline	Mean (SD)	14.1 (2.32)	16.8 (3.83)	14.3 (3.20)
Week 1	Change from Baseline			
	Estimate (SE)	-1.5 (0.72)	-0.8 (0.76)	-0.5 (0.68)
	95% CI	(-3.0, -0.1)	(-2.3, 0.8)	(-1.9, 0.9)
	Treatment Difference			
	Estimate (SE)		0.8 (1.07)	1.1 (0.99)
	95% CI		(-1.4, 3.0)	(-1.0, 3.1)
	p-value		0.469	0.296
Week 2	Change from Baseline			
	Estimate (SE)	-2.1 (0.84)	-1.4 (0.88)	-1.0 (0.79)
	95% CI	(-3.8, -0.4)	(-3.2, 0.4)	(-2.6, 0.6)
	Treatment Difference			
	Estimate (SE)		0.7 (1.24)	1.1 (1.15)
	95% CI		(-1.8, 3.3)	(-1.3, 3.5)
	p-value		0.566	0.342
Week 4	Change from Baseline			
	Estimate (SE)	-2.4 (0.86)	-2.7 (0.93)	-2.1 (0.79)
	95% CI	(-4.2, -0.6)	(-4.6, -0.8)	(-3.7, -0.5)
	Treatment Difference			
	Estimate (SE)		-0.3 (1.29)	0.3 (1.16)
	95% CI		(-3.0, 2.3)	(-2.1, 2.7)
	p-value		0.796	0.809
Week 6	Change from Baseline			
	Estimate (SE)	-2.9 (0.85)	-3.2 (0.96)	-2.0 (0.78)
	95% CI	(-4.6, -1.1)	(-5.2, -1.2)	(-3.6, -0.4)
	Treatment Difference			
	Estimate (SE)		-0.3 (1.30)	0.9 (1.15)
	95% CI		(-3.0, 2.4)	(-1.5, 3.3)

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
	p-value		0.821	0.451
	Effect size		0.122	0.361

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	Number of subjects analysed	7	7	7
Baseline	Mean (SD)	14.1 (1.35)	17.7 (4.31)	14.6 (4.28)
Week 1	Change from Baseline			
	Estimate (SE)	0.6 (0.86)	-1.0 (0.89)	0.5 (0.85)
	95% CI	(-1.2, 2.4)	(-2.9, 0.9)	(-1.3, 2.3)
	Treatment Difference			
	Estimate (SE)		-1.6 (1.29)	-0.1 (1.19)
	95% CI		(-4.3, 1.1)	(-2.6, 2.4)
	p-value		0.235	0.962
Week 2	Change from Baseline			
	Estimate (SE)	0.4 (0.73)	-1.8 (0.75)	-0.6 (0.70)
	95% CI	(-1.2, 2.0)	(-3.4, -0.1)	(-2.1, 1.0)
	Treatment Difference			
	Estimate (SE)		-2.2 (1.10)	-1.0 (0.99)
	95% CI		(-4.6, 0.2)	(-3.1, 1.2)
	p-value		0.073	0.350
Week 4	Change from Baseline			
	Estimate (SE)	0.6 (1.09)	-1.3 (1.08)	-1.4 (1.05)
	95% CI	(-1.8, 3.0)	(-3.7, 1.0)	(-3.7, 0.9)
	Treatment Difference			
	Estimate (SE)		-1.9 (1.57)	-2.1 (1.50)
	95% CI		(-5.3, 1.5)	(-5.3, 1.2)
	p-value		0.240	0.196
Week 6	Change from Baseline			
	Estimate (SE)	1.2 (1.28)	-1.9 (1.17)	-1.6 (1.14)
	95% CI	(-1.6, 4.0)	(-4.4, 0.7)	(-4.2, 0.9)
	Treatment Difference			
	Estimate (SE)		-3.1 (1.77)	-2.8 (1.70)

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	95% CI		(-6.9, 0.8)	(-6.5, 0.9)
	p-value		0.107	0.120
	Effect size		1.092	1.012

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
	Number of subjects analysed	55	58	53
Baseline	Mean (SD)	16.3 (3.09)	17.3 (3.44)	17.4 (4.08)
Week 1	Change from Baseline			
	Estimate (SE)	-0.6 (0.31)	-1.4 (0.30)	-1.1 (0.31)
	95% CI	(-1.2, 0.0)	(-2.0, -0.8)	(-1.8, -0.5)
	Treatment Difference			
	Estimate (SE)		-0.8 (0.42)	-0.5 (0.43)
	95% CI		(-1.6, 0.1)	(-1.4, 0.3)
	p-value		0.074	0.223
Week 2	Change from Baseline			
	Estimate (SE)	-1.1 (0.38)	-1.9 (0.37)	-2.2 (0.38)
	95% CI	(-1.8, -0.3)	(-2.7, -1.2)	(-3.0, -1.5)
	Treatment Difference			
	Estimate (SE)		-0.9 (0.52)	-1.1 (0.53)
	95% CI		(-1.9, 0.2)	(-2.2, -0.1)
	p-value		0.102	0.037
Week 4	Change from Baseline			
	Estimate (SE)	-1.6 (0.43)	-2.6 (0.42)	-3.4 (0.43)
	95% CI	(-2.4, -0.7)	(-3.4, -1.7)	(-4.3, -2.6)
	Treatment Difference			
	Estimate (SE)		-1.0 (0.60)	-1.9 (0.61)
	95% CI		(-2.2, 0.2)	(-3.1, -0.7)
	p-value		0.096	0.002
Week 6	Change from Baseline			
	Estimate (SE)	-1.2 (0.50)	-2.9 (0.49)	-4.0 (0.50)
	95% CI	(-2.2, -0.2)	(-3.9, -1.9)	(-4.9, -3.0)
	Treatment Difference			

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
	Estimate (SE)		-1.7 (0.70)	-2.7 (0.71)
	95% CI		(-3.0, -0.3)	(-4.1, -1.3)
	p-value		0.018	< 0.001
	Effect size		0.489	0.796

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	Number of subjects analysed	25	22	22
Baseline	Mean (SD)	17.2 (4.03)	16.6 (3.86)	18.0 (4.16)
Week 1	Change from Baseline			
	Estimate (SE)	-1.1 (0.60)	-1.0 (0.65)	-2.2 (0.64)
	95% CI	(-2.3, 0.1)	(-2.3, 0.3)	(-3.5, -1.0)
	Treatment Difference			
	Estimate (SE)		0.1 (0.86)	-1.1 (0.87)
	95% CI		(-1.7, 1.8)	(-2.9, 0.6)
	p-value		0.939	0.197
Week 2	Change from Baseline			
	Estimate (SE)	-1.6 (0.77)	-2.9 (0.84)	-3.5 (0.82)
	95% CI	(-3.1, 0.0)	(-4.5, -1.2)	(-5.1, -1.8)
	Treatment Difference			
	Estimate (SE)		-1.3 (1.13)	-1.9 (1.12)
	95% CI		(-3.6, 1.0)	(-4.2, 0.3)
	p-value		0.252	0.094
Week 4	Change from Baseline			
	Estimate (SE)	-2.8 (0.82)	-3.2 (0.88)	-4.6 (0.86)
	95% CI	(-4.4, -1.1)	(-5.0, -1.4)	(-6.3, -2.8)
	Treatment Difference			
	Estimate (SE)		-0.4 (1.19)	-1.8 (1.18)
	95% CI		(-2.8, 1.9)	(-4.2, 0.6)
	p-value		0.719	0.135
Week 6	Change from Baseline			
	Estimate (SE)	-3.7 (0.84)	-3.7 (0.89)	-5.1 (0.88)
	95% CI	(-5.3, -2.0)	(-5.5, -1.9)	(-6.8, -3.3)

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	Treatment Difference			
	Estimate (SE)		-0.1 (1.21)	-1.4 (1.21)
	95% CI		(-2.5, 2.4)	(-3.8, 1.0)
	p-value		0.950	0.255
	Effect size		0.019	0.343

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	Number of subjects analysed	14	13	12
Baseline	Mean (SD)	15.1 (2.54)	17.8 (3.08)	16.5 (2.91)
Week 1	Change from Baseline			
	Estimate (SE)	-0.5 (0.69)	-0.5 (0.69)	-1.4 (0.69)
	95% CI	(-1.9, 0.9)	(-1.9, 0.9)	(-2.8, 0.0)
	Treatment Difference			
	Estimate (SE)		0.0 (0.99)	-0.9 (0.94)
	95% CI		(-2.0, 2.0)	(-2.8, 1.0)
	p-value		0.994	0.364
Week 2	Change from Baseline			
	Estimate (SE)	0.1 (0.81)	-0.9 (0.81)	-1.9 (0.82)
	95% CI	(-1.6, 1.7)	(-2.5, 0.8)	(-3.6, -0.2)
	Treatment Difference			
	Estimate (SE)		-0.9 (1.16)	-2.0 (1.12)
	95% CI		(-3.3, 1.4)	(-4.3, 0.3)
	p-value		0.430	0.091
Week 4	Change from Baseline			
	Estimate (SE)	-0.6 (0.79)	-2.3 (0.79)	-2.0 (0.79)
	95% CI	(-2.3, 1.0)	(-3.9, -0.7)	(-3.6, -0.3)
	Treatment Difference			
	Estimate (SE)		-1.6 (1.13)	-1.3 (1.08)
	95% CI		(-4.0, 0.7)	(-3.6, 0.9)
	p-value		0.157	0.233
Week 6	Change from Baseline			
	Estimate (SE)	-0.9 (0.95)	-2.7 (0.95)	-1.8 (0.95)
	95% CI	(-2.9, 1.0)	(-4.6, -0.7)	(-3.8, 0.1)

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	Treatment Difference			
	Estimate (SE)		-1.7 (1.35)	-0.9 (1.32)
	95% CI		(-4.5, 1.0)	(-3.6, 1.9)
	p-value		0.208	0.521
	Effect size		0.540	0.265

Country: Taiwan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
	Number of subjects analysed	14	15	17
Baseline	Mean (SD)	16.9 (4.97)	14.8 (3.08)	13.6 (2.65)
Week 1	Change from Baseline			
	Estimate (SE)	0.5 (0.48)	-1.9 (0.44)	-1.6 (0.43)
	95% CI	(-0.4, 1.5)	(-2.8, -1.0)	(-2.5, -0.7)
	Treatment Difference			
	Estimate (SE)		-2.4 (0.65)	-2.1 (0.66)
	95% CI		(-3.7, -1.1)	(-3.5, -0.8)
	p-value		< 0.001	0.003
Week 2	Change from Baseline			
	Estimate (SE)	0.9 (0.62)	-2.9 (0.58)	-2.4 (0.56)
	95% CI	(-0.4, 2.1)	(-4.0, -1.7)	(-3.6, -1.3)
	Treatment Difference			
	Estimate (SE)		-3.8 (0.85)	-3.3 (0.85)
	95% CI		(-5.5, -2.0)	(-5.0, -1.6)
	p-value		< 0.001	< 0.001
Week 4	Change from Baseline			
	Estimate (SE)	0.7 (0.79)	-2.8 (0.65)	-3.3 (0.62)
	95% CI	(-0.9, 2.3)	(-4.1, -1.5)	(-4.6, -2.1)
	Treatment Difference			
	Estimate (SE)		-3.5 (1.02)	-4.0 (1.02)
	95% CI		(-5.6, -1.5)	(-6.1, -2.0)
	p-value		0.001	< 0.001
Week 6	Change from Baseline			
	Estimate (SE)	0.6 (0.96)	-2.1 (0.74)	-3.1 (0.71)

Country: Taiwan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
	95% CI	(-1.4, 2.5)	(-3.6, -0.6)	(-4.5, -1.6)
	Treatment Difference			
	Estimate (SE)		-2.6 (1.21)	-3.6 (1.21)
	95% CI		(-5.1, -0.2)	(-6.1, -1.2)
	p-value		0.036	0.004
	Effect size		0.962	1.330

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	Number of subjects analysed	14	17	15
Baseline	Mean (SD)	16.7 (1.98)	17.4 (1.54)	17.7 (1.58)
Week 1	Change from Baseline			
	Estimate (SE)	-0.6 (0.35)	-1.1 (0.31)	-0.8 (0.33)
	95% CI	(-1.3, 0.1)	(-1.8, -0.5)	(-1.4, -0.1)
	Treatment Difference			
	Estimate (SE)		-0.5 (0.46)	-0.2 (0.48)
	95% CI		(-1.5, 0.4)	(-1.1, 0.8)
	p-value		0.250	0.741
Week 2	Change from Baseline			
	Estimate (SE)	-0.7 (0.39)	-1.7 (0.35)	-1.8 (0.37)
	95% CI	(-1.5, 0.1)	(-2.4, -1.0)	(-2.6, -1.1)
	Treatment Difference			
	Estimate (SE)		-1.1 (0.52)	-1.2 (0.54)
	95% CI		(-2.1, 0.0)	(-2.3, -0.1)
	p-value		0.049	0.039
Week 4	Change from Baseline			
	Estimate (SE)	-1.8 (0.51)	-2.4 (0.45)	-2.8 (0.48)
	95% CI	(-2.8, -0.7)	(-3.3, -1.5)	(-3.8, -1.9)
	Treatment Difference			
	Estimate (SE)		-0.6 (0.67)	-1.1 (0.70)
	95% CI		(-2.0, 0.7)	(-2.5, 0.3)
	p-value		0.358	0.130
Week 6	Change from Baseline			

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	Estimate (SE)	-1.1 (0.53)	-3.0 (0.47)	-2.9 (0.50)
	95% CI	(-2.1, 0.0)	(-4.0, -2.1)	(-3.9, -1.9)
	Treatment Difference			
	Estimate (SE)		-2.0 (0.71)	-1.8 (0.73)
	95% CI		(-3.4, -0.5)	(-3.3, -0.4)
	p-value		0.008	0.016
	Effect size		1.018	0.952

Estimates, standard errors (SE), confidence intervals (CI) and p-values are based on a mixed model for repeated measures (MMRM) of the change from baseline score, with fixed effects for treatment group, visit as a categorical variable, baseline score, pooled center, and treatment by visit interaction. An unstructured matrix (UN) is used for within subject covariance matrix. For models that failed to converge under an unstructured matrix, a different covariance matrix was used instead: heterogeneous Toeplitz (TOEPH), heterogeneous first-order autoregressive (ARH(1)), and Toeplitz (TOEP). These alternative covariance structures use a robust sandwich estimator for the standard error of the fixed effect estimates. In case that all models were failed to converge, 'Non-calculable' is presented instead of model estimates.

表 2.7.3.6-21　PANSS 5 因子モデル別合計スコア変化量　Positive Symptoms
（20 試験：二重盲検治療期、MMRM、実施国別）

mITT Population

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
	Number of subjects analysed	51	55	56
Baseline	Mean (SD)	14.7 (2.46)	15.2 (3.39)	14.7 (2.94)
Week 1	Change from Baseline			
	Estimate (SE)	-0.5 (0.25)	-0.5 (0.24)	-1.2 (0.24)
	95% CI	(-1.0, 0.0)	(-0.9, 0.0)	(-1.7, -0.7)
	Treatment Difference			
	Estimate (SE)		0.1 (0.34)	-0.6 (0.34)
	95% CI		(-0.6, 0.8)	(-1.3, 0.0)
	p-value		0.807	0.059
Week 2	Change from Baseline			
	Estimate (SE)	-1.0 (0.34)	-0.9 (0.33)	-1.8 (0.32)
	95% CI	(-1.6, -0.3)	(-1.5, -0.2)	(-2.5, -1.2)
	Treatment Difference			
	Estimate (SE)		0.1 (0.46)	-0.9 (0.46)
	95% CI		(-0.8, 1.0)	(-1.8, 0.0)
	p-value		0.861	0.062

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
Week 4	Change from Baseline			
	Estimate (SE)	-1.1 (0.47)	-1.5 (0.45)	-2.5 (0.43)
	95% CI	(-2.0, -0.2)	(-2.4, -0.6)	(-3.4, -1.7)
	Treatment Difference			
	Estimate (SE)		-0.4 (0.65)	-1.4 (0.64)
	95% CI		(-1.7, 0.9)	(-2.7, -0.2)
	p-value		0.544	0.027
Week 6	Change from Baseline			
	Estimate (SE)	-1.3 (0.54)	-1.6 (0.52)	-2.8 (0.49)
	95% CI	(-2.4, -0.2)	(-2.6, -0.6)	(-3.8, -1.8)
	Treatment Difference			
	Estimate (SE)		-0.3 (0.75)	-1.5 (0.73)
	95% CI		(-1.7, 1.2)	(-2.9, 0.0)
	p-value		0.735	0.047
	Effect size		0.073	0.424

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
	Number of subjects analysed	9	9	10
Baseline	Mean (SD)	16.1 (2.37)	15.6 (1.51)	16.5 (1.58)
Week 1	Change from Baseline			
	Estimate (SE)	-1.7 (0.50)	-0.8 (0.51)	-2.2 (0.48)
	95% CI	(-2.8, -0.7)	(-1.8, 0.3)	(-3.2, -1.2)
	Treatment Difference			
	Estimate (SE)		1.0 (0.71)	-0.4 (0.69)
	95% CI		(-0.5, 2.4)	(-1.9, 1.0)
	p-value		0.194	0.525
Week 2	Change from Baseline			
	Estimate (SE)	-2.3 (0.66)	-1.8 (0.70)	-2.4 (0.63)
	95% CI	(-3.7, -0.9)	(-3.2, -0.3)	(-3.7, -1.1)
	Treatment Difference			
	Estimate (SE)		0.5 (0.96)	-0.1 (0.92)
	95% CI		(-1.5, 2.5)	(-2.0, 1.8)
	p-value		0.609	0.921

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
Week 4	Change from Baseline			
	Estimate (SE)	-3.5 (0.78)	-4.0 (0.84)	-3.8 (0.71)
	95% CI	(-5.1, -1.9)	(-5.7, -2.3)	(-5.2, -2.3)
	Treatment Difference			
	Estimate (SE)		-0.5 (1.15)	-0.3 (1.06)
	95% CI		(-2.9, 1.9)	(-2.5, 1.9)
	p-value		0.669	0.809
Week 6	Change from Baseline			
	Estimate (SE)	-4.3 (0.82)	-5.0 (0.91)	-4.8 (0.74)
	95% CI	(-6.0, -2.6)	(-6.9, -3.1)	(-6.3, -3.2)
	Treatment Difference			
	Estimate (SE)		-0.8 (1.23)	-0.5 (1.10)
	95% CI		(-3.3, 1.8)	(-2.8, 1.8)
	p-value		0.544	0.661
	Effect size		0.326	0.211

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	Number of subjects analysed	7	7	7
Baseline	Mean (SD)	14.7 (4.57)	16.7 (3.45)	14.0 (2.94)
Week 1	Change from Baseline			
	Estimate (SE)	-0.1 (0.69)	-0.9 (0.72)	0.0 (0.70)
	95% CI	(-1.6, 1.3)	(-2.4, 0.6)	(-1.4, 1.5)
	Treatment Difference			
	Estimate (SE)		-0.8 (1.00)	0.2 (0.97)
	95% CI		(-2.9, 1.3)	(-1.9, 2.2)
	p-value		0.452	0.869
Week 2	Change from Baseline			
	Estimate (SE)	0.1 (0.90)	-2.2 (0.92)	-1.3 (0.91)
	95% CI	(-1.9, 2.0)	(-4.2, -0.3)	(-3.2, 0.7)
	Treatment Difference			
	Estimate (SE)		-2.3 (1.29)	-1.3 (1.27)
	95% CI		(-5.0, 0.5)	(-4.0, 1.4)

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	p-value		0.097	0.315
Week 4	Change from Baseline			
	Estimate (SE)	-0.8 (0.96)	-1.4 (0.92)	-1.5 (0.90)
	95% CI	(-2.8, 1.3)	(-3.4, 0.5)	(-3.5, 0.4)
	Treatment Difference			
	Estimate (SE)		-0.6 (1.34)	-0.8 (1.31)
	95% CI		(-3.5, 2.2)	(-3.6, 2.0)
	p-value		0.636	0.568
Week 6	Change from Baseline			
	Estimate (SE)	-0.5 (1.72)	-0.5 (1.44)	-2.5 (1.43)
	95% CI	(-4.2, 3.1)	(-3.6, 2.6)	(-5.6, 0.6)
	Treatment Difference			
	Estimate (SE)		0.1 (2.25)	-2.0 (2.23)
	95% CI		(-4.7, 4.9)	(-6.8, 2.8)
	p-value		0.980	0.386
	Effect size		0.017	0.594

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
	Number of subjects analysed	55	58	53
Baseline	Mean (SD)	16.6 (2.80)	17.3 (2.89)	17.1 (3.80)
Week 1	Change from Baseline			
	Estimate (SE)	-1.9 (0.34)	-1.9 (0.34)	-1.7 (0.35)
	95% CI	(-2.6, -1.2)	(-2.6, -1.2)	(-2.4, -1.0)
	Treatment Difference			
	Estimate (SE)		0.0 (0.47)	0.2 (0.48)
	95% CI		(-0.9, 0.9)	(-0.8, 1.1)
	p-value		0.984	0.692
Week 2	Change from Baseline			
	Estimate (SE)	-3.0 (0.44)	-2.8 (0.43)	-3.2 (0.45)
	95% CI	(-3.8, -2.1)	(-3.6, -1.9)	(-4.1, -2.3)
	Treatment Difference			
	Estimate (SE)		0.2 (0.61)	-0.2 (0.62)

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
	95% CI		(-1.0, 1.4)	(-1.4, 1.0)
	p-value		0.739	0.741
Week 4	Change from Baseline			
	Estimate (SE)	-4.0 (0.56)	-3.6 (0.55)	-4.9 (0.57)
	95% CI	(-5.1, -2.9)	(-4.7, -2.5)	(-6.0, -3.8)
	Treatment Difference			
	Estimate (SE)		0.4 (0.78)	-0.9 (0.79)
	95% CI		(-1.2, 1.9)	(-2.5, 0.7)
	p-value		0.647	0.257
Week 6	Change from Baseline			
	Estimate (SE)	-4.2 (0.62)	-4.2 (0.62)	-5.8 (0.63)
	95% CI	(-5.4, -3.0)	(-5.4, -3.0)	(-7.1, -4.6)
	Treatment Difference			
	Estimate (SE)		0.0 (0.87)	-1.6 (0.88)
	95% CI		(-1.7, 1.7)	(-3.4, 0.1)
	p-value		0.992	0.067
	Effect size		0.002	0.381

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	Number of subjects analysed	25	22	22
Baseline	Mean (SD)	15.9 (2.62)	16.5 (2.99)	15.9 (3.19)
Week 1	Change from Baseline			
	Estimate (SE)	-1.2 (0.61)	-1.6 (0.66)	-2.4 (0.65)
	95% CI	(-2.5, 0.0)	(-2.9, -0.3)	(-3.7, -1.1)
	Treatment Difference			
	Estimate (SE)		-0.3 (0.89)	-1.2 (0.89)
	95% CI		(-2.1, 1.4)	(-3.0, 0.6)
	p-value		0.698	0.184
Week 2	Change from Baseline			
	Estimate (SE)	-2.6 (0.70)	-2.6 (0.75)	-3.1 (0.74)
	95% CI	(-4.0, -1.2)	(-4.1, -1.1)	(-4.5, -1.6)
	Treatment Difference			

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	Estimate (SE)		0.0 (1.01)	-0.5 (1.01)
	95% CI		(-2.0, 2.1)	(-2.5, 1.6)
	p-value		0.977	0.655
Week 4	Change from Baseline			
	Estimate (SE)	-2.6 (0.73)	-4.4 (0.78)	-4.7 (0.76)
	95% CI	(-4.0, -1.1)	(-6.0, -2.8)	(-6.2, -3.2)
	Treatment Difference			
	Estimate (SE)		-1.8 (1.05)	-2.2 (1.04)
	95% CI		(-4.0, 0.3)	(-4.2, -0.1)
	p-value		0.084	0.043
Week 6	Change from Baseline			
	Estimate (SE)	-3.6 (0.81)	-4.3 (0.86)	-5.2 (0.86)
	95% CI	(-5.2, -2.0)	(-6.0, -2.5)	(-6.9, -3.4)
	Treatment Difference			
	Estimate (SE)		-0.7 (1.18)	-1.6 (1.17)
	95% CI		(-3.0, 1.7)	(-3.9, 0.8)
	p-value		0.582	0.191
	Effect size		0.165	0.394

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	Number of subjects analysed	14	13	12
Baseline	Mean (SD)	16.6 (2.87)	16.2 (2.58)	15.5 (3.12)
Week 1	Change from Baseline			
	Estimate (SE)	-0.9 (0.51)	-0.4 (0.53)	-0.9 (0.56)
	95% CI	(-1.9, 0.2)	(-1.4, 0.7)	(-2.1, 0.2)
	Treatment Difference			
	Estimate (SE)		0.5 (0.72)	0.0 (0.75)
	95% CI		(-1.0, 2.0)	(-1.6, 1.5)
	p-value		0.485	0.959
Week 2	Change from Baseline			
	Estimate (SE)	-1.0 (0.79)	-1.7 (0.82)	-2.3 (0.85)
	95% CI	(-2.6, 0.6)	(-3.3, 0.0)	(-4.1, -0.6)

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	Treatment Difference			
	Estimate (SE)		-0.6 (1.13)	-1.3 (1.15)
	95% CI		(-2.9, 1.7)	(-3.6, 1.1)
	p-value		0.591	0.271
Week 4	Change from Baseline			
	Estimate (SE)	-2.4 (0.82)	-2.2 (0.84)	-3.1 (0.86)
	95% CI	(-4.1, -0.8)	(-3.9, -0.5)	(-4.8, -1.3)
	Treatment Difference			
	Estimate (SE)		0.3 (1.17)	-0.6 (1.19)
	95% CI		(-2.1, 2.7)	(-3.1, 1.8)
	p-value		0.818	0.594
Week 6	Change from Baseline			
	Estimate (SE)	-2.8 (0.91)	-2.9 (0.93)	-2.9 (0.95)
	95% CI	(-4.7, -1.0)	(-4.8, -1.0)	(-4.8, -1.0)
	Treatment Difference			
	Estimate (SE)		0.0 (1.30)	-0.1 (1.31)
	95% CI		(-2.7, 2.6)	(-2.8, 2.6)
	p-value		0.983	0.956
	Effect size		0.009	0.023

Country: Taiwan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
	Number of subjects analysed	14	15	17
Baseline	Mean (SD)	16.2 (3.36)	15.2 (3.38)	16.5 (2.79)
Week 1	Change from Baseline			
	Estimate (SE)	-0.5 (0.58)	-2.5 (0.58)	-2.3 (0.54)
	95% CI	(-1.7, 0.6)	(-3.7, -1.3)	(-3.4, -1.2)
	Treatment Difference			
	Estimate (SE)		-2.0 (0.82)	-1.7 (0.79)
	95% CI		(-3.6, -0.3)	(-3.3, -0.1)
	p-value		0.022	0.033
Week 2	Change from Baseline			
	Estimate (SE)	-0.6 (0.70)	-4.1 (0.70)	-3.9 (0.64)
	95% CI	(-2.0, 0.8)	(-5.5, -2.7)	(-5.2, -2.6)

Country: Taiwan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
	Treatment Difference			
	Estimate (SE)		-3.5 (0.99)	-3.3 (0.95)
	95% CI		(-5.5, -1.5)	(-5.2, -1.4)
	p-value		0.001	0.001
Week 4	Change from Baseline			
	Estimate (SE)	-0.8 (0.88)	-4.0 (0.77)	-5.1 (0.73)
	95% CI	(-2.6, 1.0)	(-5.6, -2.4)	(-6.6, -3.7)
	Treatment Difference			
	Estimate (SE)		-3.2 (1.17)	-4.3 (1.14)
	95% CI		(-5.6, -0.8)	(-6.6, -2.0)
	p-value		0.010	< 0.001
Week 6	Change from Baseline			
	Estimate (SE)	-0.8 (0.98)	-4.4 (0.80)	-5.7 (0.75)
	95% CI	(-2.8, 1.2)	(-6.0, -2.8)	(-7.2, -4.1)
	Treatment Difference			
	Estimate (SE)		-3.6 (1.27)	-4.9 (1.23)
	95% CI		(-6.2, -1.0)	(-7.4, -2.4)
	p-value		0.007	< 0.001
	Effect size		1.242	1.675

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	Number of subjects analysed	14	17	15
Baseline	Mean (SD)	15.6 (3.41)	15.4 (2.29)	15.0 (2.07)
Week 1	Change from Baseline			
	Estimate (SE)	-0.1 (0.48)	-1.1 (0.43)	-0.7 (0.45)
	95% CI	(-1.1, 0.9)	(-2.0, -0.2)	(-1.6, 0.2)
	Treatment Difference			
	Estimate (SE)		-1.0 (0.63)	-0.6 (0.65)
	95% CI		(-2.3, 0.2)	(-1.9, 0.7)
	p-value		0.112	0.359
Week 2	Change from Baseline			
	Estimate (SE)	-1.2 (0.53)	-1.5 (0.48)	-1.8 (0.50)

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	95% CI	(-2.2, -0.1)	(-2.5, -0.5)	(-2.8, -0.8)
	Treatment Difference			
	Estimate (SE)		-0.4 (0.70)	-0.7 (0.73)
	95% CI		(-1.8, 1.1)	(-2.1, 0.8)
	p-value		0.612	0.365
Week 4	Change from Baseline			
	Estimate (SE)	-2.4 (0.73)	-3.1 (0.65)	-2.4 (0.68)
	95% CI	(-3.9, -0.9)	(-4.4, -1.8)	(-3.8, -1.0)
	Treatment Difference			
	Estimate (SE)		-0.7 (0.96)	0.0 (1.00)
	95% CI		(-2.7, 1.2)	(-2.0, 2.0)
	p-value		0.461	0.970
Week 6	Change from Baseline			
	Estimate (SE)	-2.4 (0.78)	-3.6 (0.69)	-2.8 (0.73)
	95% CI	(-3.9, -0.8)	(-5.0, -2.2)	(-4.3, -1.3)
	Treatment Difference			
	Estimate (SE)		-1.2 (1.03)	-0.5 (1.06)
	95% CI		(-3.3, 0.9)	(-2.6, 1.7)
	p-value		0.243	0.661
	Effect size		0.432	0.167

Estimates, standard errors (SE), confidence intervals (CI) and p-values are based on a mixed model for repeated measures (MMRM) of the change from baseline score, with fixed effects for treatment group, visit as a categorical variable, baseline score, pooled center, and treatment by visit interaction. An unstructured matrix (UN) is used for within subject covariance matrix. For models that failed to converge under an unstructured matrix, a different covariance matrix was used instead: heterogeneous Toeplitz (TOEPH), heterogeneous first-order autoregressive (ARH(1)), and Toeplitz (TOEP). These alternative covariance structures use a robust sandwich estimator for the standard error of the fixed effect estimates. In case that all models were failed to converge, 'Non-calculable' is presented instead of model estimates.

表 2.7.3.6-22　PANSS 5 因子モデル別合計スコア変化量　Anxiety/Depression
（20 試験：二重盲検治療期、MMRM、実施国別）

mITT Population

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
	Number of subjects analysed	51	55	56
Baseline	Mean (SD)	16.0 (3.97)	15.9 (4.20)	16.1 (3.67)
Week 1	Change from Baseline			

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
	Estimate (SE)	-0.8 (0.31)	-0.5 (0.30)	-1.0 (0.30)
	95% CI	(-1.5, -0.2)	(-1.1, 0.1)	(-1.6, -0.4)
	Treatment Difference			
	Estimate (SE)		0.4 (0.43)	-0.2 (0.43)
	95% CI		(-0.5, 1.2)	(-1.0, 0.6)
	p-value		0.413	0.647
Week 2	Change from Baseline			
	Estimate (SE)	-1.2 (0.40)	-1.0 (0.39)	-1.9 (0.38)
	95% CI	(-2.0, -0.4)	(-1.8, -0.2)	(-2.6, -1.2)
	Treatment Difference			
	Estimate (SE)		0.2 (0.55)	-0.7 (0.55)
	95% CI		(-0.9, 1.3)	(-1.8, 0.4)
	p-value		0.725	0.198
Week 4	Change from Baseline			
	Estimate (SE)	-1.7 (0.48)	-1.6 (0.46)	-2.5 (0.43)
	95% CI	(-2.6, -0.7)	(-2.5, -0.7)	(-3.4, -1.6)
	Treatment Difference			
	Estimate (SE)		0.1 (0.65)	-0.8 (0.64)
	95% CI		(-1.2, 1.4)	(-2.1, 0.4)
	p-value		0.903	0.189
Week 6	Change from Baseline			
	Estimate (SE)	-1.7 (0.49)	-1.5 (0.47)	-2.5 (0.44)
	95% CI	(-2.7, -0.7)	(-2.5, -0.6)	(-3.4, -1.7)
	Treatment Difference			
	Estimate (SE)		0.2 (0.67)	-0.9 (0.66)
	95% CI		(-1.2, 1.5)	(-2.2, 0.4)
	p-value		0.806	0.194
	Effect size		0.054	0.278

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
	Number of subjects analysed	9	9	10
Baseline	Mean (SD)	11.2 (4.66)	11.4 (4.61)	12.1 (3.98)

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
Week 1	Change from Baseline			
	Estimate (SE)	0.2 (0.46)	-1.1 (0.46)	-0.3 (0.44)
	95% CI	(-0.7, 1.2)	(-2.0, -0.1)	(-1.2, 0.6)
	Treatment Difference			
	Estimate (SE)		-1.3 (0.65)	-0.5 (0.64)
	95% CI		(-2.6, 0.1)	(-1.9, 0.8)
	p-value		0.061	0.399
Week 2	Change from Baseline			
	Estimate (SE)	0.0 (0.65)	-1.7 (0.68)	-0.9 (0.61)
	95% CI	(-1.3, 1.3)	(-3.1, -0.3)	(-2.2, 0.3)
	Treatment Difference			
	Estimate (SE)		-1.7 (0.94)	-0.9 (0.89)
	95% CI		(-3.6, 0.3)	(-2.8, 0.9)
	p-value		0.085	0.310
Week 4	Change from Baseline			
	Estimate (SE)	-0.6 (0.81)	-2.8 (0.87)	-1.4 (0.73)
	95% CI	(-2.3, 1.1)	(-4.6, -1.0)	(-2.9, 0.1)
	Treatment Difference			
	Estimate (SE)		-2.2 (1.19)	-0.8 (1.09)
	95% CI		(-4.7, 0.2)	(-3.1, 1.4)
	p-value		0.075	0.446
Week 6	Change from Baseline			
	Estimate (SE)	-2.2 (0.73)	-3.8 (0.81)	-1.5 (0.65)
	95% CI	(-3.7, -0.7)	(-5.5, -2.1)	(-2.9, -0.2)
	Treatment Difference			
	Estimate (SE)		-1.6 (1.09)	0.7 (0.98)
	95% CI		(-3.8, 0.7)	(-1.4, 2.7)
	p-value		0.165	0.489
	Effect size		0.762	0.336

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	Number of subjects analysed	7	7	7
Baseline	Mean (SD)	15.6 (2.57)	17.4 (2.88)	14.4 (1.51)

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
Week 1	Change from Baseline			
	Estimate (SE)	1.1 (0.83)	-0.1 (0.88)	-0.3 (0.86)
	95% CI	(-0.7, 2.8)	(-1.9, 1.8)	(-2.1, 1.6)
	Treatment Difference			
	Estimate (SE)		-1.1 (1.22)	-1.3 (1.19)
	95% CI		(-3.7, 1.5)	(-3.9, 1.2)
	p-value		0.373	0.290
Week 2	Change from Baseline			
	Estimate (SE)	0.1 (0.80)	-1.1 (0.84)	-0.7 (0.83)
	95% CI	(-1.7, 1.8)	(-3.0, 0.7)	(-2.5, 1.1)
	Treatment Difference			
	Estimate (SE)		-1.2 (1.18)	-0.8 (1.15)
	95% CI		(-3.8, 1.3)	(-3.3, 1.7)
	p-value		0.319	0.492
Week 4	Change from Baseline			
	Estimate (SE)	-0.3 (1.15)	-0.6 (1.11)	-0.9 (1.10)
	95% CI	(-2.8, 2.2)	(-3.0, 1.8)	(-3.3, 1.5)
	Treatment Difference			
	Estimate (SE)		-0.3 (1.60)	-0.6 (1.58)
	95% CI		(-3.8, 3.1)	(-4.0, 2.8)
	p-value		0.840	0.720
Week 6	Change from Baseline			
	Estimate (SE)	-0.4 (1.63)	-1.8 (1.44)	-1.7 (1.44)
	95% CI	(-4.0, 3.1)	(-5.0, 1.3)	(-4.8, 1.4)
	Treatment Difference			
	Estimate (SE)		-1.4 (2.18)	-1.3 (2.18)
	95% CI		(-6.1, 3.4)	(-6.0, 3.5)
	p-value		0.538	0.570
	Effect size		0.411	0.378

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
	Number of subjects analysed	55	58	53

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
Baseline	Mean (SD)	13.1 (3.73)	14.3 (3.42)	14.0 (3.74)
Week 1	Change from Baseline			
	Estimate (SE)	-0.9 (0.28)	-0.8 (0.28)	-1.2 (0.28)
	95% CI	(-1.5, -0.4)	(-1.3, -0.2)	(-1.8, -0.7)
	Treatment Difference			
	Estimate (SE)		0.2 (0.39)	-0.3 (0.39)
	95% CI		(-0.6, 0.9)	(-1.0, 0.5)
	p-value		0.696	0.498
Week 2	Change from Baseline			
	Estimate (SE)	-1.6 (0.34)	-1.9 (0.33)	-2.1 (0.33)
	95% CI	(-2.2, -0.9)	(-2.5, -1.2)	(-2.8, -1.5)
	Treatment Difference			
	Estimate (SE)		-0.3 (0.46)	-0.6 (0.47)
	95% CI		(-1.2, 0.6)	(-1.5, 0.4)
	p-value		0.510	0.236
Week 4	Change from Baseline			
	Estimate (SE)	-2.1 (0.39)	-2.4 (0.39)	-3.1 (0.39)
	95% CI	(-2.9, -1.3)	(-3.1, -1.6)	(-3.9, -2.3)
	Treatment Difference			
	Estimate (SE)		-0.3 (0.55)	-1.0 (0.55)
	95% CI		(-1.3, 0.8)	(-2.1, 0.1)
	p-value		0.632	0.069
Week 6	Change from Baseline			
	Estimate (SE)	-2.3 (0.45)	-3.3 (0.44)	-3.6 (0.45)
	95% CI	(-3.2, -1.5)	(-4.2, -2.5)	(-4.5, -2.8)
	Treatment Difference			
	Estimate (SE)		-1.0 (0.62)	-1.3 (0.63)
	95% CI		(-2.2, 0.2)	(-2.6, -0.1)
	p-value		0.114	0.040
	Effect size		0.327	0.431

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	Number of subjects analysed	25	22	22

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
Baseline	Mean (SD)	12.0 (2.80)	12.9 (3.31)	11.5 (2.99)
Week 1	Change from Baseline			
	Estimate (SE)	-1.0 (0.40)	-1.4 (0.44)	-1.3 (0.43)
	95% CI	(-1.8, -0.2)	(-2.3, -0.5)	(-2.2, -0.4)
	Treatment Difference			
	Estimate (SE)		-0.4 (0.59)	-0.3 (0.58)
	95% CI		(-1.6, 0.7)	(-1.5, 0.8)
	p-value		0.465	0.554
Week 2	Change from Baseline			
	Estimate (SE)	-1.9 (0.52)	-1.8 (0.56)	-1.8 (0.54)
	95% CI	(-2.9, -0.8)	(-2.9, -0.7)	(-2.9, -0.8)
	Treatment Difference			
	Estimate (SE)		0.0 (0.75)	0.0 (0.75)
	95% CI		(-1.5, 1.6)	(-1.5, 1.5)
	p-value		0.955	0.976
Week 4	Change from Baseline			
	Estimate (SE)	-2.0 (0.57)	-3.1 (0.61)	-2.7 (0.59)
	95% CI	(-3.1, -0.8)	(-4.3, -1.9)	(-3.9, -1.5)
	Treatment Difference			
	Estimate (SE)		-1.1 (0.82)	-0.7 (0.81)
	95% CI		(-2.8, 0.5)	(-2.3, 0.9)
	p-value		0.174	0.384
Week 6	Change from Baseline			
	Estimate (SE)	-2.8 (0.55)	-3.6 (0.58)	-2.8 (0.57)
	95% CI	(-3.9, -1.7)	(-4.8, -2.4)	(-4.0, -1.7)
	Treatment Difference			
	Estimate (SE)		-0.8 (0.79)	0.0 (0.79)
	95% CI		(-2.4, 0.8)	(-1.6, 1.5)
	p-value		0.309	0.950
	Effect size		0.310	0.019

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	Number of subjects analysed	14	13	12
Baseline	Mean (SD)	16.3 (2.87)	16.0 (4.64)	15.8 (2.77)
Week 1	Change from Baseline			
	Estimate (SE)	-0.8 (0.63)	-0.6 (0.66)	-1.6 (0.68)
	95% CI	(-2.1, 0.4)	(-2.0, 0.7)	(-3.0, -0.2)
	Treatment Difference			
	Estimate (SE)		0.2 (0.89)	-0.8 (0.91)
	95% CI		(-1.6, 2.0)	(-2.6, 1.1)
	p-value		0.807	0.416
Week 2	Change from Baseline			
	Estimate (SE)	-0.8 (0.84)	-1.4 (0.88)	-2.0 (0.90)
	95% CI	(-2.5, 1.0)	(-3.2, 0.4)	(-3.8, -0.2)
	Treatment Difference			
	Estimate (SE)		-0.6 (1.20)	-1.2 (1.22)
	95% CI		(-3.1, 1.9)	(-3.7, 1.3)
	p-value		0.619	0.319
Week 4	Change from Baseline			
	Estimate (SE)	-2.5 (1.13)	-2.1 (1.16)	-2.3 (1.18)
	95% CI	(-4.8, -0.2)	(-4.5, 0.2)	(-4.7, 0.2)
	Treatment Difference			
	Estimate (SE)		0.4 (1.61)	0.3 (1.62)
	95% CI		(-2.9, 3.7)	(-3.1, 3.6)
	p-value		0.814	0.867
Week 6	Change from Baseline			
	Estimate (SE)	-2.6 (1.10)	-2.0 (1.11)	-2.4 (1.12)
	95% CI	(-4.9, -0.4)	(-4.3, 0.2)	(-4.7, -0.1)
	Treatment Difference			
	Estimate (SE)		0.6 (1.55)	0.2 (1.56)
	95% CI		(-2.6, 3.8)	(-3.0, 3.4)
	p-value		0.697	0.888
	Effect size		0.158	0.058

Country: Taiwan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
	Number of subjects analysed	14	15	17
Baseline	Mean (SD)	14.1 (3.50)	14.4 (2.85)	13.4 (2.47)
Week 1	Change from Baseline			
	Estimate (SE)	-0.3 (0.52)	-2.0 (0.51)	-0.7 (0.48)
	95% CI	(-1.4, 0.7)	(-3.0, -0.9)	(-1.7, 0.2)
	Treatment Difference			
	Estimate (SE)		-1.7 (0.72)	-0.4 (0.71)
	95% CI		(-3.1, -0.2)	(-1.9, 1.0)
	p-value		0.027	0.542
Week 2	Change from Baseline			
	Estimate (SE)	0.3 (0.59)	-4.2 (0.57)	-1.8 (0.54)
	95% CI	(-0.9, 1.5)	(-5.3, -3.0)	(-2.9, -0.7)
	Treatment Difference			
	Estimate (SE)		-4.4 (0.82)	-2.1 (0.80)
	95% CI		(-6.1, -2.8)	(-3.7, -0.5)
	p-value		< 0.001	0.013
Week 4	Change from Baseline			
	Estimate (SE)	-1.6 (0.85)	-4.2 (0.67)	-3.0 (0.64)
	95% CI	(-3.3, 0.1)	(-5.6, -2.9)	(-4.3, -1.7)
	Treatment Difference			
	Estimate (SE)		-2.7 (1.08)	-1.5 (1.07)
	95% CI		(-4.9, -0.5)	(-3.6, 0.7)
	p-value		0.019	0.181
Week 6	Change from Baseline			
	Estimate (SE)	-1.7 (0.88)	-3.6 (0.68)	-3.7 (0.64)
	95% CI	(-3.5, 0.0)	(-5.0, -2.2)	(-5.0, -2.4)
	Treatment Difference			
	Estimate (SE)		-1.9 (1.12)	-1.9 (1.09)
	95% CI		(-4.1, 0.4)	(-4.1, 0.3)
	p-value		0.106	0.086
	Effect size		0.748	0.779

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	Number of subjects analysed	14	17	15
Baseline	Mean (SD)	13.9 (2.91)	13.0 (3.08)	12.6 (2.85)
Week 1	Change from Baseline			
	Estimate (SE)	-1.0 (0.36)	-1.0 (0.33)	-0.9 (0.35)
	95% CI	(-1.7, -0.2)	(-1.7, -0.3)	(-1.6, -0.2)
	Treatment Difference			
	Estimate (SE)		0.0 (0.48)	0.1 (0.50)
	95% CI		(-1.0, 1.0)	(-0.9, 1.1)
	p-value		0.974	0.855
Week 2	Change from Baseline			
	Estimate (SE)	-1.9 (0.57)	-1.2 (0.51)	-2.1 (0.54)
	95% CI	(-3.0, -0.8)	(-2.3, -0.2)	(-3.2, -1.0)
	Treatment Difference			
	Estimate (SE)		0.7 (0.76)	-0.2 (0.78)
	95% CI		(-0.9, 2.2)	(-1.8, 1.4)
	p-value		0.378	0.821
Week 4	Change from Baseline			
	Estimate (SE)	-2.8 (0.75)	-1.9 (0.67)	-1.9 (0.71)
	95% CI	(-4.3, -1.3)	(-3.3, -0.6)	(-3.4, -0.5)
	Treatment Difference			
	Estimate (SE)		0.9 (1.00)	0.9 (1.03)
	95% CI		(-1.1, 2.9)	(-1.2, 3.0)
	p-value		0.377	0.400
Week 6	Change from Baseline			
	Estimate (SE)	-3.0 (0.75)	-2.0 (0.66)	-1.9 (0.70)
	95% CI	(-4.5, -1.5)	(-3.3, -0.6)	(-3.3, -0.5)
	Treatment Difference			
	Estimate (SE)		1.0 (1.00)	1.1 (1.03)
	95% CI		(-1.0, 3.0)	(-1.0, 3.2)
	p-value		0.323	0.288
	Effect size		0.367	0.407

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)

Estimates, standard errors (SE), confidence intervals (CI) and p-values are based on a mixed model for repeated measures (MMRM) of the change from baseline score, with fixed effects for treatment group, visit as a categorical variable, baseline score, pooled center, and treatment by visit interaction. An unstructured matrix (UN) is used for within subject covariance matrix. For models that failed to converge under an unstructured matrix, a different covariance matrix was used instead: heterogeneous Toeplitz (TOEPH), heterogeneous first-order autoregressive (ARH(1)), and Toeplitz (TOEP). These alternative covariance structures use a robust sandwich estimator for the standard error of the fixed effect estimates. In case that all models were failed to converge, 'Non-calculable' is presented instead of model estimates.

表 2.7.3.6-23　CGI-S スコア変化量（20 試験：二重盲検治療期、MMRM、実施国別）

mITT Population

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
	Number of subjects analysed	51	55	56
Baseline	Mean (SD)	4.59 (0.753)	4.64 (0.825)	4.77 (0.894)
Week 1	Change from Baseline			
	Estimate (SE)	-0.13 (0.086)	-0.09 (0.084)	-0.28 (0.084)
	95% CI	(-0.30, 0.04)	(-0.26, 0.07)	(-0.44, -0.11)
	Treatment Difference			
	Estimate (SE)		0.04 (0.118)	-0.15 (0.118)
	95% CI		(-0.20, 0.27)	(-0.38, 0.09)
	p-value		0.760	0.215
Week 2	Change from Baseline			
	Estimate (SE)	-0.21 (0.130)	-0.20 (0.125)	-0.34 (0.123)
	95% CI	(-0.47, 0.04)	(-0.45, 0.05)	(-0.59, -0.10)
	Treatment Difference			
	Estimate (SE)		0.01 (0.179)	-0.13 (0.178)
	95% CI		(-0.34, 0.37)	(-0.48, 0.22)
	p-value		0.947	0.470
Week 4	Change from Baseline			
	Estimate (SE)	-0.32 (0.159)	-0.34 (0.153)	-0.65 (0.148)
	95% CI	(-0.63, 0.00)	(-0.64, -0.04)	(-0.94, -0.36)
	Treatment Difference			
	Estimate (SE)		-0.02 (0.219)	-0.34 (0.216)
	95% CI		(-0.46, 0.41)	(-0.76, 0.09)
	p-value		0.917	0.123

Country: Japan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
Week 6	Change from Baseline			
	Estimate (SE)	-0.45 (0.168)	-0.33 (0.160)	-0.77 (0.153)
	95% CI	(-0.78, -0.11)	(-0.64, -0.01)	(-1.07, -0.47)
	Treatment Difference			
	Estimate (SE)		0.12 (0.231)	-0.32 (0.227)
	95% CI		(-0.34, 0.58)	(-0.77, 0.13)
	p-value		0.605	0.157
	Effect size		0.110	0.296

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
	Number of subjects analysed	9	9	10
Baseline	Mean (SD)	5.22 (0.667)	5.67 (0.707)	5.10 (0.568)
Week 1	Change from Baseline			
	Estimate (SE)	-0.80 (0.177)	-0.18 (0.187)	-0.23 (0.170)
	95% CI	(-1.16, -0.43)	(-0.57, 0.20)	(-0.58, 0.12)
	Treatment Difference			
	Estimate (SE)		0.62 (0.260)	0.57 (0.243)
	95% CI		(0.08, 1.15)	(0.07, 1.07)
	p-value		0.026	0.028
Week 2	Change from Baseline			
	Estimate (SE)	-1.13 (0.290)	-0.68 (0.308)	-0.33 (0.276)
	95% CI	(-1.73, -0.53)	(-1.31, -0.05)	(-0.90, 0.24)
	Treatment Difference			
	Estimate (SE)		0.45 (0.424)	0.81 (0.399)
	95% CI		(-0.42, 1.32)	(-0.02, 1.63)
	p-value		0.298	0.055
Week 4	Change from Baseline			
	Estimate (SE)	-1.51 (0.359)	-1.25 (0.381)	-0.83 (0.334)
	95% CI	(-2.26, -0.77)	(-2.03, -0.46)	(-1.52, -0.13)
	Treatment Difference			
	Estimate (SE)		0.27 (0.525)	0.69 (0.489)
	95% CI		(-0.82, 1.35)	(-0.33, 1.70)
	p-value		0.617	0.175

Country: China Visit	Statistics (Covariance matrix=UN)	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
Week 6	Change from Baseline			
	Estimate (SE)	-1.74 (0.295)	-2.26 (0.333)	-1.23 (0.268)
	95% CI	(-2.36, -1.12)	(-2.95, -1.57)	(-1.79, -0.66)
	Treatment Difference			
	Estimate (SE)		-0.52 (0.446)	0.52 (0.398)
	95% CI		(-1.45, 0.41)	(-0.32, 1.35)
	p-value		0.260	0.211
	Effect size		0.613	0.612

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	Number of subjects analysed	7	7	7
Baseline	Mean (SD)	4.43 (0.787)	5.43 (1.134)	4.43 (0.787)
Week 1	Change from Baseline			
	Estimate (SE)	0.38 (0.350)	-0.75 (0.374)	0.38 (0.350)
	95% CI	(-0.37, 1.12)	(-1.54, 0.05)	(-0.37, 1.12)
	Treatment Difference			
	Estimate (SE)		-1.12 (0.535)	0.00 (0.482)
	95% CI		(-2.26, 0.01)	(-1.03, 1.03)
	p-value		0.052	> 0.999
Week 2	Change from Baseline			
	Estimate (SE)	0.06 (0.474)	-1.24 (0.494)	-0.08 (0.475)
	95% CI	(-0.97, 1.08)	(-2.30, -0.18)	(-1.11, 0.94)
	Treatment Difference			
	Estimate (SE)		-1.29 (0.702)	-0.14 (0.663)
	95% CI		(-2.80, 0.21)	(-1.57, 1.30)
	p-value		0.086	0.838
Week 4	Change from Baseline			
	Estimate (SE)	0.05 (0.547)	-0.91 (0.547)	-0.26 (0.531)
	95% CI	(-1.13, 1.22)	(-2.08, 0.27)	(-1.41, 0.89)
	Treatment Difference			
	Estimate (SE)		-0.95 (0.789)	-0.31 (0.754)
	95% CI		(-2.64, 0.74)	(-1.94, 1.32)

Country: Korea Visit	Statistics (Covariance matrix=UN)	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	p-value		0.246	0.690
Week 6	Change from Baseline			
	Estimate (SE)	0.50 (0.702)	-0.85 (0.677)	-0.15 (0.661)
	95% CI	(-0.98, 1.99)	(-2.30, 0.60)	(-1.57, 1.27)
	Treatment Difference			
	Estimate (SE)		-1.36 (0.993)	-0.65 (0.954)
	95% CI		(-3.46, 0.75)	(-2.69, 1.39)
	p-value		0.191	0.506
	Effect size		0.820	0.394

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
	Number of subjects analysed	55	58	53
Baseline	Mean (SD)	4.89 (0.658)	4.91 (0.629)	5.15 (0.533)
Week 1	Change from Baseline			
	Estimate (SE)	-0.21 (0.075)	-0.32 (0.073)	-0.36 (0.076)
	95% CI	(-0.36, -0.07)	(-0.47, -0.18)	(-0.51, -0.21)
	Treatment Difference			
	Estimate (SE)		-0.11 (0.102)	-0.15 (0.106)
	95% CI		(-0.31, 0.09)	(-0.35, 0.06)
	p-value		0.294	0.171
Week 2	Change from Baseline			
	Estimate (SE)	-0.61 (0.110)	-0.56 (0.107)	-0.67 (0.111)
	95% CI	(-0.83, -0.40)	(-0.77, -0.35)	(-0.89, -0.45)
	Treatment Difference			
	Estimate (SE)		0.06 (0.152)	-0.05 (0.156)
	95% CI		(-0.24, 0.36)	(-0.36, 0.26)
	p-value		0.705	0.738
Week 4	Change from Baseline			
	Estimate (SE)	-0.68 (0.134)	-0.78 (0.131)	-1.06 (0.134)
	95% CI	(-0.94, -0.41)	(-1.04, -0.52)	(-1.32, -0.79)
	Treatment Difference			
	Estimate (SE)		-0.10 (0.186)	-0.38 (0.189)

Country: Malaysia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
	95% CI		(-0.47, 0.27)	(-0.75, 0.00)
	p-value		0.595	0.047
Week 6	Change from Baseline			
	Estimate (SE)	-0.78 (0.152)	-0.83 (0.150)	-1.18 (0.153)
	95% CI	(-1.08, -0.48)	(-1.13, -0.53)	(-1.49, -0.88)
	Treatment Difference			
	Estimate (SE)		-0.05 (0.213)	-0.41 (0.215)
	95% CI		(-0.47, 0.37)	(-0.83, 0.02)
	p-value		0.800	0.060
	Effect size		0.052	0.394

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	Number of subjects analysed	25	22	22
Baseline	Mean (SD)	4.80 (0.707)	4.82 (0.853)	4.86 (0.640)
Week 1	Change from Baseline			
	Estimate (SE)	-0.19 (0.128)	-0.20 (0.138)	-0.53 (0.137)
	95% CI	(-0.44, 0.07)	(-0.47, 0.08)	(-0.80, -0.26)
	Treatment Difference			
	Estimate (SE)		-0.01 (0.185)	-0.34 (0.185)
	95% CI		(-0.38, 0.36)	(-0.72, 0.03)
	p-value		0.950	0.067
Week 2	Change from Baseline			
	Estimate (SE)	-0.44 (0.154)	-0.58 (0.165)	-0.71 (0.162)
	95% CI	(-0.75, -0.14)	(-0.91, -0.25)	(-1.04, -0.39)
	Treatment Difference			
	Estimate (SE)		-0.14 (0.223)	-0.27 (0.222)
	95% CI		(-0.58, 0.31)	(-0.71, 0.17)
	p-value		0.545	0.230
Week 4	Change from Baseline			
	Estimate (SE)	-0.37 (0.174)	-0.87 (0.187)	-0.94 (0.183)
	95% CI	(-0.71, -0.02)	(-1.24, -0.49)	(-1.31, -0.58)
	Treatment Difference			

Country: Philippines Visit	Statistics (Covariance matrix=UN)	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	Estimate (SE)		-0.50 (0.253)	-0.57 (0.251)
	95% CI		(-1.01, 0.01)	(-1.08, -0.07)
	p-value		0.052	0.026
Week 6	Change from Baseline			
	Estimate (SE)	-0.66 (0.197)	-0.96 (0.208)	-1.20 (0.207)
	95% CI	(-1.05, -0.26)	(-1.38, -0.54)	(-1.61, -0.78)
	Treatment Difference			
	Estimate (SE)		-0.30 (0.284)	-0.54 (0.284)
	95% CI		(-0.87, 0.26)	(-1.11, 0.03)
	p-value		0.288	0.062
	Effect size		0.321	0.568

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	Number of subjects analysed	14	13	12
Baseline	Mean (SD)	4.71 (0.469)	4.92 (0.760)	4.67 (0.778)
Week 1	Change from Baseline			
	Estimate (SE)	-0.03 (0.152)	0.04 (0.158)	-0.12 (0.166)
	95% CI	(-0.34, 0.28)	(-0.28, 0.36)	(-0.46, 0.22)
	Treatment Difference			
	Estimate (SE)		0.07 (0.216)	-0.09 (0.219)
	95% CI		(-0.37, 0.51)	(-0.53, 0.36)
	p-value		0.745	0.695
Week 2	Change from Baseline			
	Estimate (SE)	-0.05 (0.164)	0.03 (0.171)	-0.29 (0.177)
	95% CI	(-0.39, 0.29)	(-0.33, 0.38)	(-0.65, 0.08)
	Treatment Difference			
	Estimate (SE)		0.08 (0.234)	-0.24 (0.235)
	95% CI		(-0.40, 0.56)	(-0.72, 0.25)
	p-value		0.740	0.327
Week 4	Change from Baseline			
	Estimate (SE)	-0.46 (0.219)	-0.56 (0.223)	-0.45 (0.228)
	95% CI	(-0.91, -0.01)	(-1.02, -0.09)	(-0.93, 0.02)

Country: Russia Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	Treatment Difference			
	Estimate (SE)		-0.10 (0.310)	0.01 (0.311)
	95% CI		(-0.74, 0.55)	(-0.64, 0.65)
	p-value		0.760	0.983
Week 6	Change from Baseline			
	Estimate (SE)	-0.53 (0.225)	-0.69 (0.226)	-0.54 (0.228)
	95% CI	(-0.99, -0.07)	(-1.15, -0.22)	(-1.01, -0.07)
	Treatment Difference			
	Estimate (SE)		-0.16 (0.317)	-0.01 (0.315)
	95% CI		(-0.81, 0.50)	(-0.65, 0.64)
	p-value		0.627	0.981
	Effect size		0.201	0.010

Country: Taiwan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
	Number of subjects analysed	14	15	17
Baseline	Mean (SD)	5.21 (0.975)	4.67 (0.724)	5.12 (0.928)
Week 1	Change from Baseline			
	Estimate (SE)	-0.14 (0.187)	-0.62 (0.186)	-0.64 (0.171)
	95% CI	(-0.52, 0.24)	(-1.00, -0.25)	(-0.99, -0.30)
	Treatment Difference			
	Estimate (SE)		-0.48 (0.268)	-0.50 (0.251)
	95% CI		(-1.02, 0.06)	(-1.01, 0.00)
	p-value		0.080	0.052
Week 2	Change from Baseline			
	Estimate (SE)	-0.09 (0.217)	-1.15 (0.214)	-1.28 (0.196)
	95% CI	(-0.53, 0.35)	(-1.59, -0.72)	(-1.68, -0.88)
	Treatment Difference			
	Estimate (SE)		-1.06 (0.308)	-1.19 (0.290)
	95% CI		(-1.69, -0.44)	(-1.78, -0.60)
	p-value		0.002	< 0.001
Week 4	Change from Baseline			
	Estimate (SE)	-0.33 (0.337)	-1.05 (0.293)	-1.46 (0.276)
	95% CI	(-1.01, 0.36)	(-1.65, -0.45)	(-2.03, -0.90)

Country: Taiwan Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
	Treatment Difference			
	Estimate (SE)		-0.72 (0.448)	-1.14 (0.433)
	95% CI		(-1.63, 0.19)	(-2.02, -0.25)
	p-value		0.116	0.013
Week 6	Change from Baseline			
	Estimate (SE)	-0.29 (0.332)	-1.04 (0.277)	-1.75 (0.257)
	95% CI	(-0.96, 0.38)	(-1.61, -0.48)	(-2.28, -1.23)
	Treatment Difference			
	Estimate (SE)		-0.75 (0.434)	-1.46 (0.418)
	95% CI		(-1.63, 0.13)	(-2.31, -0.61)
	p-value		0.091	0.001
	Effect size		0.746	1.447

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	Number of subjects analysed	14	17	15
Baseline	Mean (SD)	4.57 (0.514)	4.65 (0.606)	4.87 (0.352)
Week 1	Change from Baseline			
	Estimate (SE)	-0.07 (0.105)	-0.11 (0.096)	-0.31 (0.103)
	95% CI	(-0.28, 0.14)	(-0.30, 0.09)	(-0.52, -0.10)
	Treatment Difference			
	Estimate (SE)		-0.04 (0.139)	-0.24 (0.147)
	95% CI		(-0.32, 0.24)	(-0.54, 0.05)
	p-value		0.782	0.107
Week 2	Change from Baseline			
	Estimate (SE)	-0.14 (0.146)	-0.34 (0.133)	-0.71 (0.142)
	95% CI	(-0.44, 0.15)	(-0.61, -0.07)	(-1.00, -0.43)
	Treatment Difference			
	Estimate (SE)		-0.20 (0.195)	-0.57 (0.204)
	95% CI		(-0.60, 0.19)	(-0.98, -0.16)
	p-value		0.306	0.008
Week 4	Change from Baseline			
	Estimate (SE)	-0.45 (0.206)	-0.64 (0.184)	-0.64 (0.197)

Country: Ukraine Visit	Statistics (Covariance matrix=UN)	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	95% CI	(-0.86, -0.03)	(-1.01, -0.27)	(-1.04, -0.25)
	Treatment Difference			
	Estimate (SE)		-0.19 (0.275)	-0.20 (0.285)
	95% CI		(-0.75, 0.36)	(-0.77, 0.38)
	p-value		0.491	0.490
Week 6	Change from Baseline			
	Estimate (SE)	-0.45 (0.214)	-0.87 (0.191)	-0.64 (0.204)
	95% CI	(-0.88, -0.01)	(-1.26, -0.49)	(-1.06, -0.23)
	Treatment Difference			
	Estimate (SE)		-0.43 (0.286)	-0.20 (0.296)
	95% CI		(-1.00, 0.15)	(-0.79, 0.40)
	p-value		0.144	0.508
	Effect size		0.543	0.253

Estimates, standard errors (SE), confidence intervals (CI) and p-values are based on a mixed model for repeated measures (MMRM) of the change from baseline score, with fixed effects for treatment group, visit as a categorical variable, baseline score, pooled center, and treatment by visit interaction. An unstructured matrix (UN) is used for within subject covariance matrix. For models that failed to converge under an unstructured matrix, a different covariance matrix was used instead: heterogeneous Toeplitz (TOEPH), heterogeneous first-order autoregressive (ARH(1)), and Toeplitz (TOEP). These alternative covariance structures use a robust sandwich estimator for the standard error of the fixed effect estimates. In case that all models were failed to converge, 'Non-calculable' is presented instead of model estimates.

表 2.7.3.6-24　PANSS responder の割合（20 試験：二重盲検治療期、実施国別）

mITT Population

Country: Japan Visit	Statistics	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
Week 6 (LOCF)	n	51	55	56
	>=20% Improvement from Baseline, n (%)	12 (23.5)	16 (29.1)	23 (41.1)
	Odds Ratio		1.34	2.23
	95% CI		(0.55, 3.29)	(0.93, 5.33)
	p-value		0.523	0.071
	>=30% Improvement from Baseline, n (%)	6 (11.8)	12 (21.8)	14 (25.0)
	Odds Ratio		2.21	2.41
	95% CI		(0.74, 6.67)	(0.82, 7.12)
	p-value		0.157	0.111
	>=40% Improvement from Baseline, n (%)	3 (5.9)	7 (12.7)	11 (19.6)
	Odds Ratio *1		2.30	3.76
	95% CI *1		(0.56, 9.49)	(0.98, 14.47)

Country: Japan Visit	Statistics	PLCB (N = 51)	40MG (N = 55)	80MG (N = 56)
	p-value *1		0.251	0.054
	>=50% Improvement from Baseline, n (%)	0	3 (5.5)	7 (12.5)
	Odds Ratio *2		Non-calculable	Non-calculable
	95% CI *2		Non-calculable	Non-calculable
	p-value *2		Non-calculable	Non-calculable

Country: China Visit	Statistics	PLCB (N = 9)	40MG (N = 9)	80MG (N = 10)
Week 6 (LOCF)	n	9	9	10
	>=20% Improvement from Baseline, n (%)	6 (66.7)	7 (77.8)	4 (40.0)
	Odds Ratio		1.90	0.24
	95% CI		(0.21, 17.40)	(0.03, 1.99)
	p-value		0.571	0.186
	>=30% Improvement from Baseline, n (%)	4 (44.4)	4 (44.4)	3 (30.0)
	Odds Ratio		1.23	0.25
	95% CI		(0.14, 10.76)	(0.02, 3.26)
	p-value		0.849	0.289
	>=40% Improvement from Baseline, n (%)	3 (33.3)	4 (44.4)	3 (30.0)
	Odds Ratio		2.37	0.46
	95% CI		(0.24, 23.85)	(0.03, 6.30)
	p-value		0.463	0.561
	>=50% Improvement from Baseline, n (%)	2 (22.2)	1 (11.1)	2 (20.0)
	Odds Ratio		0.49	0.38
	95% CI		(0.02, 12.07)	(0.01, 9.94)
	p-value		0.666	0.559

Country: Korea Visit	Statistics	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
Week 6 (LOCF)	n	7	7	7
	>=20% Improvement from Baseline, n (%)	1 (14.3)	2 (28.6)	3 (42.9)
	Odds Ratio		0.85	4.88
	95% CI		(0.04, 19.59)	(0.30, 78.17)
	p-value		0.920	0.262
	>=30% Improvement from Baseline, n (%)	1 (14.3)	2 (28.6)	2 (28.6)
	Odds Ratio		1.31	2.32

Country: Korea Visit	Statistics	PLCB (N = 7)	40MG (N = 7)	80MG (N = 7)
	95% CI		(0.06, 26.91)	(0.15, 35.41)
	p-value		0.859	0.546
	>=40% Improvement from Baseline, n (%)	0	1 (14.3)	1 (14.3)
	Odds Ratio *2		Non-calculable	Non-calculable
	95% CI *2		Non-calculable	Non-calculable
	p-value *2		Non-calculable	Non-calculable
	>=50% Improvement from Baseline, n (%)	0	0	0
	Odds Ratio *2		Non-calculable	Non-calculable
	95% CI *2		Non-calculable	Non-calculable
	p-value *2		Non-calculable	Non-calculable

Country: Malaysia Visit	Statistics	PLCB (N = 55)	40MG (N = 58)	80MG (N = 53)
Week 6 (LOCF)	n	55	58	53
	>=20% Improvement from Baseline, n (%)	26 (47.3)	31 (53.4)	37 (69.8)
	Odds Ratio		1.49	3.10
	95% CI		(0.68, 3.24)	(1.34, 7.15)
	p-value		0.317	0.008
	>=30% Improvement from Baseline, n (%)	18 (32.7)	23 (39.7)	30 (56.6)
	Odds Ratio		1.58	3.29
	95% CI		(0.70, 3.57)	(1.42, 7.60)
	p-value		0.268	0.005
	>=40% Improvement from Baseline, n (%)	14 (25.5)	16 (27.6)	20 (37.7)
	Odds Ratio		1.37	2.33
	95% CI		(0.56, 3.35)	(0.95, 5.69)
	p-value		0.494	0.064
	>=50% Improvement from Baseline, n (%)	8 (14.5)	11 (19.0)	17 (32.1)
	Odds Ratio		1.71	4.05
	95% CI		(0.59, 5.01)	(1.42, 11.54)
	p-value		0.326	0.009

Country: Philippines Visit	Statistics	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
Week 6 (LOCF)	n	25	22	22

Country: Philippines Visit	Statistics	PLCB (N = 25)	40MG (N = 22)	80MG (N = 22)
	>=20% Improvement from Baseline, n (%)	17 (68.0)	15 (68.2)	14 (63.6)
	Odds Ratio		0.98	0.82
	95% CI		(0.28, 3.49)	(0.23, 2.86)
	p-value		0.977	0.754
	>=30% Improvement from Baseline, n (%)	11 (44.0)	10 (45.5)	12 (54.5)
	Odds Ratio		1.03	1.61
	95% CI		(0.32, 3.34)	(0.49, 5.25)
	p-value		0.964	0.434
	>=40% Improvement from Baseline, n (%)	7 (28.0)	8 (36.4)	9 (40.9)
	Odds Ratio		1.40	2.10
	95% CI		(0.37, 5.34)	(0.55, 8.03)
	p-value		0.619	0.279
	>=50% Improvement from Baseline, n (%)	5 (20.0)	7 (31.8)	8 (36.4)
	Odds Ratio		1.88	2.98
	95% CI		(0.44, 8.03)	(0.69, 12.91)
	p-value		0.395	0.145

Country: Russia Visit	Statistics	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
Week 6 (LOCF)	n	14	13	12
	>=20% Improvement from Baseline, n (%)	8 (57.1)	6 (46.2)	5 (41.7)
	Odds Ratio		0.60	0.51
	95% CI		(0.12, 2.91)	(0.10, 2.54)
	p-value		0.527	0.412
	>=30% Improvement from Baseline, n (%)	5 (35.7)	4 (30.8)	3 (25.0)
	Odds Ratio		0.57	0.51
	95% CI		(0.10, 3.41)	(0.08, 3.01)
	p-value		0.538	0.453
	>=40% Improvement from Baseline, n (%)	1 (7.1)	2 (15.4)	1 (8.3)
	Odds Ratio		2.41	1.19
	95% CI		(0.19, 30.67)	(0.07, 21.43)
	p-value		0.499	0.907
	>=50% Improvement from Baseline, n (%)	0	0	1 (8.3)
	Odds Ratio *2		Non-calculable	Non-calculable
	95% CI *2		Non-calculable	Non-calculable

Country: Russia Visit	Statistics	PLCB (N = 14)	40MG (N = 13)	80MG (N = 12)
	p-value *2		Non-calculable	Non-calculable

Country: Taiwan Visit	Statistics	PLCB (N = 14)	40MG (N = 15)	80MG (N = 17)
Week 6 (LOCF)	n	14	15	17
	>=20% Improvement from Baseline, n (%)	3 (21.4)	10 (66.7)	13 (76.5)
	Odds Ratio		10.11	18.93
	95% CI		(1.33, 76.51)	(2.41, 148.58)
	p-value		0.025	0.005
	>=30% Improvement from Baseline, n (%)	3 (21.4)	9 (60.0)	12 (70.6)
	Odds Ratio		7.83	15.28
	95% CI		(1.02, 60.10)	(1.94, 120.19)
	p-value		0.048	0.010
	>=40% Improvement from Baseline, n (%)	2 (14.3)	8 (53.3)	8 (47.1)
	Odds Ratio		12.10	9.45
	95% CI		(1.40, 104.81)	(1.16, 76.92)
	p-value		0.024	0.036
	>=50% Improvement from Baseline, n (%)	0	3 (20.0)	4 (23.5)
	Odds Ratio *2		Non-calculable	Non-calculable
	95% CI *2		Non-calculable	Non-calculable
	p-value *2		Non-calculable	Non-calculable

Country: Ukraine Visit	Statistics	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
Week 6 (LOCF)	n	14	17	15
	>=20% Improvement from Baseline, n (%)	7 (50.0)	12 (70.6)	8 (53.3)
	Odds Ratio		2.50	1.30
	95% CI		(0.53, 11.94)	(0.28, 6.04)
	p-value		0.249	0.739
	>=30% Improvement from Baseline, n (%)	4 (28.6)	8 (47.1)	4 (26.7)
	Odds Ratio		2.34	1.05
	95% CI		(0.46, 12.08)	(0.18, 6.27)
	p-value		0.308	0.953
	>=40% Improvement from Baseline, n (%)	2 (14.3)	3 (17.6)	2 (13.3)
	Odds Ratio *1		1.54	0.99

Country: Ukraine Visit	Statistics	PLCB (N = 14)	40MG (N = 17)	80MG (N = 15)
	95% CI *1		(0.20, 11.80)	(0.11, 8.77)
	p-value *1		0.679	0.995
	>=50% Improvement from Baseline, n (%)	0	0	1 (6.7)
	Odds Ratio *2		Non-calculable	Non-calculable
	95% CI *2		Non-calculable	Non-calculable
	p-value *2		Non-calculable	Non-calculable

Week 6 (LOCF) endpoint is the last post-baseline observation in the double-blind treatment phase up to 7 days after final application of the double-blind study treatment. Odds ratios, confidence intervals (CI) and chi-square p-values are based on logistic regression model of responder, with fixed effects for treatment group, pooled center, and baseline score. Responders are defined as patients having a greater or equal to 20%, 30%, 40% and 50% improvement from baseline. Improvements are calculated as [(post-baseline value – 30) – (baseline value – 30)] × 100 / (baseline value – 30). For logistic regression models that failed to converge, the model was attempted with only treatment group and baseline score (*1). All models were failed to converge (*2).

2.7.3.6.2　20 試験（ロナセンテープ貼付期）

表 2.7.3.6-25　人口統計学的特性及びその他のベースラインの特性
（20 試験：ロナセンテープ貼付期　Open 52 週、実施国別）

DSP-5423P Dosed Population

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Sex, n (%)					
n	27	55	57	112	139
Male	16 (59.3)	26 (47.3)	29 (50.9)	55 (49.1)	71 (51.1)
Female	11 (40.7)	29 (52.7)	28 (49.1)	57 (50.9)	68 (48.9)
Age (years)					
n	27	55	57	112	139
Mean (SD)	51.6 (14.90)	47.5 (16.03)	48.0 (17.18)	47.8 (16.55)	48.5 (16.26)
Median	53.0	49.0	52.0	49.5	50.0
Min, Max	20, 73	20, 79	22, 81	20, 81	20, 81
Age (years), n (%)					
n	27	55	57	112	139
<65	20 (74.1)	45 (81.8)	46 (80.7)	91 (81.3)	111 (79.9)
>=65	7 (25.9)	10 (18.2)	11 (19.3)	21 (18.8)	28 (20.1)
Race, n (%)					
n	27	55	57	112	139
Asian	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	27	55	57	112	139
Not Hispanic or Latino	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
Country, n (%)					
n	27	55	57	112	139
Japan	27 (100.0)	55 (100.0)	57 (100.0)	112 (100.0)	139 (100.0)
China	0	0	0	0	0
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Height (cm)					
n	27	55	57	112	139
Mean (SD)	164.08 (10.428)	161.02 (9.431)	160.78 (10.830)	160.90 (10.122)	161.52 (10.222)
Median	163.80	162.10	160.00	160.55	161.50
Min, Max	143.6, 182.0	138.0, 184.2	130.5, 182.0	130.5, 184.2	130.5, 184.2
Weight (kg)					
n	27	55	57	112	139
Mean (SD)	62.63 (15.590)	58.45 (12.770)	56.54 (13.849)	57.48 (13.305)	58.48 (13.870)
Median	61.10	56.20	54.20	56.10	57.00
Min, Max	39.6, 109.9	35.8, 87.9	31.2, 93.6	31.2, 93.6	31.2, 109.9
BMI (kg/m^2)					
n	27	55	57	112	139
Mean (SD)	23.19 (4.895)	22.51 (4.439)	21.67 (3.924)	22.08 (4.187)	22.30 (4.337)
Median	22.32	21.69	20.47	20.92	21.21
Min, Max	17.1, 33.9	15.5, 36.1	13.9, 31.1	13.9, 36.1	13.9, 36.1
Any concomitant diseases, n (%)					
n	27	55	57	112	139
Yes	24 (88.9)	47 (85.5)	52 (91.2)	99 (88.4)	123 (88.5)
No	3 (11.1)	8 (14.5)	5 (8.8)	13 (11.6)	16 (11.5)
Hospitalization status at informed consent, n (%)					
n	27	55	57	112	139
Inpatient	23 (85.2)	48 (87.3)	55 (96.5)	103 (92.0)	126 (90.6)
Within 3 months (90 days)	19 (70.4)	33 (60.0)	43 (75.4)	76 (67.9)	95 (68.3)
Over 3 months	4 (14.8)	15 (27.3)	12 (21.1)	27 (24.1)	31 (22.3)
Unknown	0	0	0	0	0
Outpatient	4 (14.8)	7 (12.7)	2 (3.5)	9 (8.0)	13 (9.4)

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Sex, n (%)					
n	8	9	10	19	27
Male	7 (87.5)	1 (11.1)	2 (20.0)	3 (15.8)	10 (37.0)
Female	1 (12.5)	8 (88.9)	8 (80.0)	16 (84.2)	17 (63.0)
Age (years)					

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
n	8	9	10	19	27
Mean (SD)	47.6 (17.61)	41.8 (15.21)	36.2 (13.73)	38.8 (14.33)	41.4 (15.57)
Median	51.0	39.0	32.0	36.0	39.0
Min, Max	22, 68	24, 62	20, 60	20, 62	20, 68
Age (years), n (%)					
n	8	9	10	19	27
<65	7 (87.5)	9 (100.0)	10 (100.0)	19 (100.0)	26 (96.3)
>=65	1 (12.5)	0	0	0	1 (3.7)
Race, n (%)					
n	8	9	10	19	27
Asian	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	8	9	10	19	27
Not Hispanic or Latino	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Country, n (%)					
n	8	9	10	19	27
Japan	0	0	0	0	0
China	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	8	9	10	19	27
Mean (SD)	167.19 (6.708)	161.39 (2.759)	164.15 (8.199)	162.84 (6.245)	164.13 (6.573)
Median	166.50	160.00	162.25	160.50	163.50
Min, Max	155.0, 177.0	158.5, 166.0	154.0, 182.0	154.0, 182.0	154.0, 182.0
Weight (kg)					
n	8	9	10	19	27
Mean (SD)	68.93 (17.824)	64.67 (14.499)	67.39 (18.517)	66.10 (16.335)	66.94 (16.492)
Median	61.85	60.00	64.50	60.00	61.00
Min, Max	48.5, 103.0	50.0, 91.5	44.5, 96.5	44.5, 96.5	44.5, 103.0

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
BMI (kg/m^2)					
n	8	9	10	19	27
Mean (SD)	24.56 (5.483)	24.84 (5.645)	25.02 (6.721)	24.94 (6.063)	24.82 (5.794)
Median	22.85	23.44	23.72	23.44	22.88
Min, Max	17.2, 32.9	18.1, 36.2	17.8, 35.3	17.8, 36.2	17.2, 36.2
Any concomitant diseases, n (%)					
n	8	9	10	19	27
Yes	6 (75.0)	7 (77.8)	5 (50.0)	12 (63.2)	18 (66.7)
No	2 (25.0)	2 (22.2)	5 (50.0)	7 (36.8)	9 (33.3)
Hospitalization status at informed consent, n (%)					
n	8	9	10	19	27
Inpatient	8 (100.0)	9 (100.0)	10 (100.0)	19 (100.0)	27 (100.0)
Within 3 months (90 days)	6 (75.0)	7 (77.8)	8 (80.0)	15 (78.9)	21 (77.8)
Over 3 months	2 (25.0)	2 (22.2)	2 (20.0)	4 (21.1)	6 (22.2)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Sex, n (%)					
n	3	7	7	14	17
Male	1 (33.3)	4 (57.1)	4 (57.1)	8 (57.1)	9 (52.9)
Female	2 (66.7)	3 (42.9)	3 (42.9)	6 (42.9)	8 (47.1)
Age (years)					
n	3	7	7	14	17
Mean (SD)	51.3 (2.08)	39.7 (11.80)	40.4 (10.63)	40.1 (10.80)	42.1 (10.71)
Median	52.0	36.0	43.0	36.5	43.0
Min, Max	49, 53	27, 64	23, 56	23, 64	23, 64
Age (years), n (%)					
n	3	7	7	14	17
<65	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	3	7	7	14	17

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Asian	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	3	7	7	14	17
Not Hispanic or Latino	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
Country, n (%)					
n	3	7	7	14	17
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	3 (100.0)	7 (100.0)	7 (100.0)	14 (100.0)	17 (100.0)
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	3	7	7	14	17
Mean (SD)	155.30 (7.973)	163.51 (10.425)	168.50 (10.162)	166.01 (10.223)	164.12 (10.515)
Median	156.00	158.50	169.60	166.55	162.90
Min, Max	147.0, 162.9	152.0, 181.5	154.9, 180.5	152.0, 181.5	147.0, 181.5
Weight (kg)					
n	3	7	7	14	17
Mean (SD)	53.97 (7.900)	59.83 (21.166)	64.71 (8.051)	62.27 (15.592)	60.81 (14.696)
Median	52.20	48.20	66.80	61.65	61.60
Min, Max	47.1, 62.6	41.8, 96.8	51.1, 73.9	41.8, 96.8	41.8, 96.8
BMI (kg/m^2)					
n	3	7	7	14	17
Mean (SD)	22.37 (2.625)	21.83 (4.892)	22.78 (2.062)	22.31 (3.640)	22.32 (3.410)
Median	23.59	20.43	22.01	21.54	21.54
Min, Max	19.4, 24.2	16.6, 29.4	20.7, 25.7	16.6, 29.4	16.6, 29.4
Any concomitant diseases, n (%)					
n	3	7	7	14	17
Yes	3 (100.0)	6 (85.7)	5 (71.4)	11 (78.6)	14 (82.4)
No	0	1 (14.3)	2 (28.6)	3 (21.4)	3 (17.6)

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Hospitalization status at informed consent, n (%)					
n	3	7	7	14	17
Inpatient	3 (100.0)	7 (100.0)	6 (85.7)	13 (92.9)	16 (94.1)
Within 3 months (90 days)	2 (66.7)	7 (100.0)	5 (71.4)	12 (85.7)	14 (82.4)
Over 3 months	0	0	1 (14.3)	1 (7.1)	1 (5.9)
Unknown	1 (33.3)	0	0	0	1 (5.9)
Outpatient	0	0	1 (14.3)	1 (7.1)	1 (5.9)

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Sex, n (%)					
n	43	58	54	112	155
Male	29 (67.4)	41 (70.7)	41 (75.9)	82 (73.2)	111 (71.6)
Female	14 (32.6)	17 (29.3)	13 (24.1)	30 (26.8)	44 (28.4)
Age (years)					
n	43	58	54	112	155
Mean (SD)	40.4 (9.92)	36.9 (10.57)	35.9 (11.95)	36.4 (11.22)	37.5 (10.99)
Median	38.0	38.0	35.0	35.5	37.0
Min, Max	22, 62	19, 62	18, 69	18, 69	18, 69
Age (years), n (%)					
n	43	58	54	112	155
<65	43 (100.0)	58 (100.0)	53 (98.1)	111 (99.1)	154 (99.4)
>=65	0	0	1 (1.9)	1 (0.9)	1 (0.6)
Race, n (%)					
n	43	58	54	112	155
Asian	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	43	58	54	112	155
Not Hispanic or Latino	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Country, n (%)					
n	43	58	54	112	155
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Malaysia	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	43	58	54	112	155
Mean (SD)	163.78 (9.293)	163.27 (9.886)	163.85 (9.204)	163.55 (9.525)	163.61 (9.432)
Median	164.00	164.00	165.25	164.75	164.30
Min, Max	148.0, 186.0	125.0, 185.0	136.0, 180.0	125.0, 185.0	125.0, 186.0
Weight (kg)					
n	43	58	54	112	155
Mean (SD)	64.63 (13.887)	63.81 (15.358)	63.98 (14.815)	63.89 (15.031)	64.10 (14.682)
Median	63.00	60.00	61.25	60.45	61.00
Min, Max	44.9, 122.0	41.0, 118.0	27.9, 103.0	27.9, 118.0	27.9, 122.0
BMI (kg/m^2)					
n	43	58	54	112	155
Mean (SD)	24.19 (5.236)	24.10 (6.230)	23.83 (5.179)	23.97 (5.724)	24.03 (5.577)
Median	23.18	23.23	23.18	23.22	23.19
Min, Max	16.9, 43.7	14.5, 46.8	13.6, 35.6	13.6, 46.8	13.6, 46.8
Any concomitant diseases, n (%)					
n	43	58	54	112	155
Yes	16 (37.2)	25 (43.1)	22 (40.7)	47 (42.0)	63 (40.6)
No	27 (62.8)	33 (56.9)	32 (59.3)	65 (58.0)	92 (59.4)
Hospitalization status at informed consent, n (%)					
n	43	58	54	112	155
Inpatient	43 (100.0)	58 (100.0)	54 (100.0)	112 (100.0)	155 (100.0)
Within 3 months (90 days)	42 (97.7)	56 (96.6)	54 (100.0)	110 (98.2)	152 (98.1)
Over 3 months	1 (2.3)	2 (3.4)	0	2 (1.8)	3 (1.9)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Sex, n (%)					
n	22	22	22	44	66
Male	15 (68.2)	19 (86.4)	16 (72.7)	35 (79.5)	50 (75.8)
Female	7 (31.8)	3 (13.6)	6 (27.3)	9 (20.5)	16 (24.2)
Age (years)					
n	22	22	22	44	66
Mean (SD)	33.6 (9.94)	32.7 (9.24)	32.4 (9.07)	32.5 (9.05)	32.9 (9.29)
Median	33.0	33.0	31.0	32.5	32.5
Min, Max	19, 56	20, 57	20, 55	20, 57	19, 57
Age (years), n (%)					
n	22	22	22	44	66
<65	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	22	22	22	44	66
Asian	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	22	22	22	44	66
Not Hispanic or Latino	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Country, n (%)					
n	22	22	22	44	66
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	22	22	22	44	66
Mean (SD)	158.75 (8.570)	161.68 (6.170)	161.85 (7.570)	161.77 (6.825)	160.76 (7.523)
Median	158.50	161.80	164.75	162.80	161.00
Min, Max	137.0, 172.7	147.3, 175.0	145.0, 172.0	145.0, 175.0	137.0, 175.0

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Weight (kg)					
n	22	22	22	44	66
Mean (SD)	58.92 (10.267)	58.77 (9.044)	59.60 (7.628)	59.18 (8.279)	59.10 (8.911)
Median	56.45	56.95	58.45	58.20	57.35
Min, Max	47.5, 90.2	42.8, 79.0	48.0, 74.7	42.8, 79.0	42.8, 90.2
BMI (kg/m^2)					
n	22	22	22	44	66
Mean (SD)	23.43 (4.038)	22.46 (2.984)	22.76 (2.556)	22.61 (2.750)	22.89 (3.228)
Median	22.56	22.22	22.89	22.43	22.51
Min, Max	19.1, 37.1	15.7, 27.9	18.8, 26.9	15.7, 27.9	15.7, 37.1
Any concomitant diseases, n (%)					
n	22	22	22	44	66
Yes	3 (13.6)	2 (9.1)	4 (18.2)	6 (13.6)	9 (13.6)
No	19 (86.4)	20 (90.9)	18 (81.8)	38 (86.4)	57 (86.4)
Hospitalization status at informed consent, n (%)					
n	22	22	22	44	66
Inpatient	22 (100.0)	22 (100.0)	22 (100.0)	44 (100.0)	66 (100.0)
Within 3 months (90 days)	21 (95.5)	21 (95.5)	22 (100.0)	43 (97.7)	64 (97.0)
Over 3 months	1 (4.5)	1 (4.5)	0	1 (2.3)	2 (3.0)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Sex, n (%)					
n	10	13	12	25	35
Male	5 (50.0)	6 (46.2)	5 (41.7)	11 (44.0)	16 (45.7)
Female	5 (50.0)	7 (53.8)	7 (58.3)	14 (56.0)	19 (54.3)
Age (years)					
n	10	13	12	25	35
Mean (SD)	33.7 (12.12)	39.5 (15.20)	42.8 (10.66)	41.0 (13.05)	38.9 (13.06)
Median	32.0	37.0	44.0	40.0	37.0
Min, Max	18, 54	18, 68	23, 59	18, 68	18, 68
Age (years), n (%)					

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
n	10	13	12	25	35
<65	10 (100.0)	12 (92.3)	12 (100.0)	24 (96.0)	34 (97.1)
>=65	0	1 (7.7)	0	1 (4.0)	1 (2.9)
Race, n (%)					
n	10	13	12	25	35
Asian	0	1 (7.7)	0	1 (4.0)	1 (2.9)
White	10 (100.0)	12 (92.3)	12 (100.0)	24 (96.0)	34 (97.1)
Ethnicity, n (%)					
n	10	13	12	25	35
Not Hispanic or Latino	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Country, n (%)					
n	10	13	12	25	35
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Taiwan	0	0	0	0	0
Ukraine	0	0	0	0	0
Height (cm)					
n	10	13	12	25	35
Mean (SD)	173.80 (13.054)	166.12 (11.832)	165.17 (8.288)	165.66 (10.086)	167.99 (11.438)
Median	173.50	166.00	166.50	166.00	168.00
Min, Max	150.0, 200.0	140.0, 181.0	145.0, 174.0	140.0, 181.0	140.0, 200.0
Weight (kg)					
n	10	13	12	25	35
Mean (SD)	88.01 (31.086)	66.85 (14.129)	70.41 (17.985)	68.56 (15.854)	74.11 (22.644)
Median	77.70	65.70	67.65	65.70	69.70
Min, Max	53.0, 149.8	48.1, 86.1	50.2, 118.7	48.1, 118.7	48.1, 149.8
BMI (kg/m^2)					
n	10	13	12	25	35
Mean (SD)	29.02 (9.266)	24.27 (4.647)	26.03 (7.402)	25.11 (6.059)	26.23 (7.201)
Median	26.39	26.01	24.20	24.44	24.44
Min, Max	19.7, 44.2	16.6, 31.5	16.8, 45.8	16.6, 45.8	16.6, 45.8

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Any concomitant diseases, n (%)					
n	10	13	12	25	35
Yes	7 (70.0)	8 (61.5)	9 (75.0)	17 (68.0)	24 (68.6)
No	3 (30.0)	5 (38.5)	3 (25.0)	8 (32.0)	11 (31.4)
Hospitalization status at informed consent, n (%)					
n	10	13	12	25	35
Inpatient	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Within 3 months (90 days)	10 (100.0)	13 (100.0)	12 (100.0)	25 (100.0)	35 (100.0)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Sex, n (%)					
n	5	15	17	32	37
Male	3 (60.0)	8 (53.3)	8 (47.1)	16 (50.0)	19 (51.4)
Female	2 (40.0)	7 (46.7)	9 (52.9)	16 (50.0)	18 (48.6)
Age (years)					
n	5	15	17	32	37
Mean (SD)	42.0 (13.29)	39.1 (7.17)	43.4 (9.97)	41.4 (8.89)	41.5 (9.37)
Median	42.0	39.0	43.0	40.5	41.0
Min, Max	23, 58	25, 49	24, 61	24, 61	23, 61
Age (years), n (%)					
n	5	15	17	32	37
<65	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	5	15	17	32	37
Asian	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
White	0	0	0	0	0
Ethnicity, n (%)					
n	5	15	17	32	37
Not Hispanic or Latino	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Country, n (%)					
n	5	15	17	32	37
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Ukraine	0	0	0	0	0
Height (cm)					
n	5	15	17	32	37
Mean (SD)	159.70 (8.628)	165.29 (8.637)	162.95 (9.465)	164.04 (9.019)	163.46 (8.976)
Median	157.00	167.00	162.00	163.85	163.00
Min, Max	151.0, 173.0	148.0, 178.0	149.0, 180.0	148.0, 180.0	148.0, 180.0
Weight (kg)					
n	5	15	17	32	37
Mean (SD)	62.90 (15.892)	66.83 (15.405)	65.38 (14.400)	66.06 (14.654)	65.64 (14.635)
Median	70.00	67.00	67.50	67.25	67.50
Min, Max	42.0, 76.5	46.0, 92.0	43.2, 92.0	43.2, 92.0	42.0, 92.0
BMI (kg/m^2)					
n	5	15	17	32	37
Mean (SD)	24.42 (4.675)	24.18 (3.617)	24.60 (5.116)	24.40 (4.412)	24.41 (4.380)
Median	25.56	24.05	23.49	23.77	24.05
Min, Max	17.6, 28.6	18.9, 31.4	18.4, 37.3	18.4, 37.3	17.6, 37.3
Any concomitant diseases, n (%)					
n	5	15	17	32	37
Yes	3 (60.0)	13 (86.7)	12 (70.6)	25 (78.1)	28 (75.7)
No	2 (40.0)	2 (13.3)	5 (29.4)	7 (21.9)	9 (24.3)
Hospitalization status at informed consent, n (%)					
n	5	15	17	32	37
Inpatient	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Within 3 months (90 days)	5 (100.0)	15 (100.0)	17 (100.0)	32 (100.0)	37 (100.0)
Over 3 months	0	0	0	0	0

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Unknown	0	0	0	0	0
Outpatient	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Sex, n (%)					
n	13	17	15	32	45
Male	9 (69.2)	11 (64.7)	10 (66.7)	21 (65.6)	30 (66.7)
Female	4 (30.8)	6 (35.3)	5 (33.3)	11 (34.4)	15 (33.3)
Age (years)					
n	13	17	15	32	45
Mean (SD)	39.2 (7.69)	44.7 (9.14)	39.3 (12.60)	42.2 (11.07)	41.3 (10.21)
Median	37.0	45.0	37.0	43.0	42.0
Min, Max	26, 49	26, 60	20, 64	20, 64	20, 64
Age (years), n (%)					
n	13	17	15	32	45
<65	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
>=65	0	0	0	0	0
Race, n (%)					
n	13	17	15	32	45
Asian	0	0	0	0	0
White	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Ethnicity, n (%)					
n	13	17	15	32	45
Not Hispanic or Latino	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)
Country, n (%)					
n	13	17	15	32	45
Japan	0	0	0	0	0
China	0	0	0	0	0
Korea	0	0	0	0	0
Malaysia	0	0	0	0	0
Philippines	0	0	0	0	0
Russia	0	0	0	0	0
Taiwan	0	0	0	0	0
Ukraine	13 (100.0)	17 (100.0)	15 (100.0)	32 (100.0)	45 (100.0)

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Height (cm)					
n	13	17	15	32	45
Mean (SD)	171.15 (8.830)	172.74 (6.982)	170.53 (5.963)	171.70 (6.517)	171.54 (7.159)
Median	174.00	173.00	168.00	172.00	173.00
Min, Max	155.0, 184.0	163.5, 183.0	162.0, 183.0	162.0, 183.0	155.0, 184.0
Weight (kg)					
n	13	17	15	32	45
Mean (SD)	75.36 (9.774)	75.62 (13.790)	72.66 (11.540)	74.23 (12.670)	74.56 (11.808)
Median	73.00	70.50	68.80	70.00	71.00
Min, Max	61.3, 94.0	55.5, 112.0	54.3, 91.4	54.3, 112.0	54.3, 112.0
BMI (kg/m^2)					
n	13	17	15	32	45
Mean (SD)	25.69 (2.399)	25.47 (5.167)	24.99 (3.717)	25.25 (4.481)	25.37 (3.970)
Median	25.51	23.01	24.45	23.63	24.49
Min, Max	21.8, 30.4	19.6, 37.9	17.1, 31.2	17.1, 37.9	17.1, 37.9
Any concomitant diseases, n (%)					
n	13	17	15	32	45
Yes	4 (30.8)	4 (23.5)	3 (20.0)	7 (21.9)	11 (24.4)
No	9 (69.2)	13 (76.5)	12 (80.0)	25 (78.1)	34 (75.6)
Hospitalization status at informed consent, n (%)					
n	13	17	15	32	45
Inpatient	13 (100.0)	16 (94.1)	13 (86.7)	29 (90.6)	42 (93.3)
Within 3 months (90 days)	13 (100.0)	16 (94.1)	13 (86.7)	29 (90.6)	42 (93.3)
Over 3 months	0	0	0	0	0
Unknown	0	0	0	0	0
Outpatient	0	1 (5.9)	2 (13.3)	3 (9.4)	3 (6.7)

The denominator of percentages is the number of subjects in analysis population of subgroup. The final data at Open-Week 52 was used.

表 2.7.3.6-26　疾患データ（20 試験：ロナセンテープ貼付期　Open 52 週、実施国別）

DSP-5423P Dosed Population

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Number of episodes of schizophrenia					
n	24	40	48	88	112

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Mean (SD)	3.7 (1.52)	3.3 (1.43)	3.9 (1.34)	3.6 (1.41)	3.6 (1.43)
Median	4.5	3.0	5.0	4.0	4.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	27	55	57	112	139
1	3 (11.1)	4 (7.3)	3 (5.3)	7 (6.3)	10 (7.2)
2	3 (11.1)	11 (20.0)	6 (10.5)	17 (15.2)	20 (14.4)
3	4 (14.8)	9 (16.4)	9 (15.8)	18 (16.1)	22 (15.8)
4	2 (7.4)	3 (5.5)	5 (8.8)	8 (7.1)	10 (7.2)
5 or more	12 (44.4)	13 (23.6)	25 (43.9)	38 (33.9)	50 (36.0)
Unknown	3 (11.1)	15 (27.3)	9 (15.8)	24 (21.4)	27 (19.4)
Age at the first onset of schizophrenia (years)					
n	27	53	56	109	136
Mean (SD)	29.6 (11.28)	29.5 (12.97)	28.3 (11.87)	28.9 (12.38)	29.1 (12.13)
Median	28.0	25.0	25.0	25.0	25.5
Min, Max	12, 58	12, 67	13, 60	12, 67	12, 67
Age at the first onset of schizophrenia (years), n (%)					
n	27	55	57	112	139
19 or less	6 (22.2)	12 (21.8)	16 (28.1)	28 (25.0)	34 (24.5)
20 to 29	8 (29.6)	22 (40.0)	18 (31.6)	40 (35.7)	48 (34.5)
30 to 39	8 (29.6)	7 (12.7)	11 (19.3)	18 (16.1)	26 (18.7)
40 to 49	4 (14.8)	7 (12.7)	8 (14.0)	15 (13.4)	19 (13.7)
50 or more	1 (3.7)	5 (9.1)	3 (5.3)	8 (7.1)	9 (6.5)
Unknown	0	2 (3.6)	1 (1.8)	3 (2.7)	3 (2.2)
Duration of illness (years)					
n	27	53	56	109	136
Mean (SD)	21.84 (16.942)	17.97 (14.593)	19.58 (15.449)	18.79 (14.991)	19.40 (15.380)
Median	22.88	13.68	15.82	15.35	15.39
Min, Max	0.1, 47.8	0.3, 55.2	0.7, 50.6	0.3, 55.2	0.1, 55.2
Duration of illness (years), n (%)					
n	27	55	57	112	139
<1	2 (7.4)	4 (7.3)	1 (1.8)	5 (4.5)	7 (5.0)
>=1 to <5	4 (14.8)	9 (16.4)	8 (14.0)	17 (15.2)	21 (15.1)
>=5 to <10	4 (14.8)	5 (9.1)	13 (22.8)	18 (16.1)	22 (15.8)

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
>=10 to <20	3 (11.1)	15 (27.3)	11 (19.3)	26 (23.2)	29 (20.9)
>=20 to <30	5 (18.5)	9 (16.4)	10 (17.5)	19 (17.0)	24 (17.3)
>=30	9 (33.3)	11 (20.0)	13 (22.8)	24 (21.4)	33 (23.7)
Unknown	0	2 (3.6)	1 (1.8)	3 (2.7)	3 (2.2)
Duration of current episode (months)					
n	27	55	57	112	139
Mean (SD)	12.71 (58.388)	8.38 (46.869)	9.27 (59.028)	8.84 (53.167)	9.59 (54.021)
Median	1.18	1.35	1.15	1.22	1.22
Min, Max	0.3, 304.8	0.0, 348.9	0.2, 447.0	0.0, 447.0	0.0, 447.0
Baseline PANSS total score					
n	27	55	57	112	139
Mean (SD)	102.3 (16.99)	102.7 (16.85)	104.5 (15.45)	103.6 (16.11)	103.4 (16.23)
Median	99.0	101.0	101.0	101.0	101.0
Min, Max	80, 141	80, 157	83, 155	80, 157	80, 157
PANSS composite subscale at baseline, n (%)					
n	27	55	57	112	139
Positive subscale score>Negative subscale score	9 (33.3)	23 (41.8)	21 (36.8)	44 (39.3)	53 (38.1)
Positive subscale score=Negative subscale score	1 (3.7)	2 (3.6)	5 (8.8)	7 (6.3)	8 (5.8)
Positive subscale score<Negative subscale score	17 (63.0)	30 (54.5)	31 (54.4)	61 (54.5)	78 (56.1)
Baseline PANSS total score, n (%)					
n	27	55	57	112	139
<100	14 (51.9)	27 (49.1)	25 (43.9)	52 (46.4)	66 (47.5)
>=100 to <120	9 (33.3)	19 (34.5)	24 (42.1)	43 (38.4)	52 (37.4)
>=120	4 (14.8)	9 (16.4)	8 (14.0)	17 (15.2)	21 (15.1)
Baseline CGI-S score					
n	27	55	57	112	139
Mean (SD)	4.56 (0.751)	4.64 (0.825)	4.77 (0.887)	4.71 (0.856)	4.68 (0.836)
Median	4.00	4.00	5.00	5.00	4.00
Min, Max	4, 6	3, 7	3, 7	3, 7	3, 7

Country: Japan	PLCB-to-FLEX DOSE (N = 27)	40MG-to-FLEX DOSE (N = 55)	80MG-to-FLEX DOSE (N = 57)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 139)
Baseline CGI-S score, n (%)					
n	27	55	57	112	139
1	0	0	0	0	0
2	0	0	0	0	0
3	0	1 (1.8)	1 (1.8)	2 (1.8)	2 (1.4)
4	16 (59.3)	28 (50.9)	25 (43.9)	53 (47.3)	69 (49.6)
5	7 (25.9)	17 (30.9)	19 (33.3)	36 (32.1)	43 (30.9)
6	4 (14.8)	8 (14.5)	10 (17.5)	18 (16.1)	22 (15.8)
7	0	1 (1.8)	2 (3.5)	3 (2.7)	3 (2.2)
Baseline DIEPSS total score (excluding overall severity)					
n	27	55	56	111	138
Mean (SD)	1.7 (2.88)	1.6 (3.00)	1.9 (3.54)	1.8 (3.27)	1.8 (3.19)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 10	0, 14	0, 14	0, 14	0, 14

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Number of episodes of schizophrenia					
n	8	9	10	19	27
Mean (SD)	3.8 (1.58)	3.6 (1.59)	2.7 (1.49)	3.1 (1.56)	3.3 (1.56)
Median	4.5	4.0	2.0	3.0	3.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	8	9	10	19	27
1	1 (12.5)	1 (11.1)	2 (20.0)	3 (15.8)	4 (14.8)
2	1 (12.5)	2 (22.2)	4 (40.0)	6 (31.6)	7 (25.9)
3	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
4	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
5 or more	4 (50.0)	4 (44.4)	2 (20.0)	6 (31.6)	10 (37.0)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	8	9	10	19	27
Mean (SD)	25.1 (9.30)	27.0 (7.91)	24.8 (5.83)	25.8 (6.78)	25.6 (7.43)
Median	22.5	24.0	24.5	24.0	24.0

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
Min, Max	11, 40	19, 43	17, 36	17, 43	11, 43
Age at the first onset of schizophrenia (years), n (%)					
n	8	9	10	19	27
19 or less	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
20 to 29	5 (62.5)	5 (55.6)	7 (70.0)	12 (63.2)	17 (63.0)
30 to 39	1 (12.5)	2 (22.2)	2 (20.0)	4 (21.1)	5 (18.5)
40 to 49	1 (12.5)	1 (11.1)	0	1 (5.3)	2 (7.4)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0
Duration of illness (years)					
n	8	9	10	19	27
Mean (SD)	22.62 (17.273)	14.83 (13.837)	11.43 (11.481)	13.04 (12.411)	15.88 (14.382)
Median	28.21	8.45	6.46	8.18	8.45
Min, Max	1.1, 40.1	0.5, 42.3	1.6, 34.0	0.5, 42.3	0.5, 42.3
Duration of illness (years), n (%)					
n	8	9	10	19	27
<1	0	1 (11.1)	0	1 (5.3)	1 (3.7)
>=1 to <5	2 (25.0)	1 (11.1)	5 (50.0)	6 (31.6)	8 (29.6)
>=5 to <10	1 (12.5)	3 (33.3)	1 (10.0)	4 (21.1)	5 (18.5)
>=10 to <20	0	1 (11.1)	2 (20.0)	3 (15.8)	3 (11.1)
>=20 to <30	1 (12.5)	2 (22.2)	1 (10.0)	3 (15.8)	4 (14.8)
>=30	4 (50.0)	1 (11.1)	1 (10.0)	2 (10.5)	6 (22.2)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	8	9	10	19	27
Mean (SD)	2.93 (4.417)	12.39 (33.382)	6.58 (10.952)	9.33 (23.751)	7.44 (20.116)
Median	1.38	1.28	1.49	1.38	1.38
Min, Max	0.4, 13.7	0.4, 101.4	0.9, 33.3	0.4, 101.4	0.4, 101.4
Baseline PANSS total score					
n	8	9	10	19	27
Mean (SD)	96.0 (10.07)	97.0 (8.38)	94.8 (11.82)	95.8 (10.12)	95.9 (9.91)
Median	94.0	97.0	99.5	98.0	95.0
Min, Max	84, 117	85, 113	81, 116	81, 116	81, 117

Country: China	PLCB-to-FLEX DOSE (N = 8)	40MG-to-FLEX DOSE (N = 9)	80MG-to-FLEX DOSE (N = 10)	Active-to-FLEX DOSE (N = 19)	Overall-to-FLEX DOSE (N = 27)
PANSS composite subscale at baseline, n (%)					
n	8	9	10	19	27
Positive subscale score>Negative subscale score	3 (37.5)	2 (22.2)	2 (20.0)	4 (21.1)	7 (25.9)
Positive subscale score=Negative subscale score	2 (25.0)	0	1 (10.0)	1 (5.3)	3 (11.1)
Positive subscale score<Negative subscale score	3 (37.5)	7 (77.8)	7 (70.0)	14 (73.7)	17 (63.0)
Baseline PANSS total score, n (%)					
n	8	9	10	19	27
<100	6 (75.0)	7 (77.8)	5 (50.0)	12 (63.2)	18 (66.7)
>=100 to <120	2 (25.0)	2 (22.2)	5 (50.0)	7 (36.8)	9 (33.3)
>=120	0	0	0	0	0
Baseline CGI-S score					
n	8	9	10	19	27
Mean (SD)	5.25 (0.707)	5.67 (0.707)	5.10 (0.568)	5.37 (0.684)	5.33 (0.679)
Median	5.00	6.00	5.00	5.00	5.00
Min, Max	4, 6	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	8	9	10	19	27
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	1 (12.5)	1 (11.1)	1 (10.0)	2 (10.5)	3 (11.1)
5	4 (50.0)	1 (11.1)	7 (70.0)	8 (42.1)	12 (44.4)
6	3 (37.5)	7 (77.8)	2 (20.0)	9 (47.4)	12 (44.4)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	8	9	10	19	27
Mean (SD)	2.5 (4.78)	1.0 (1.50)	1.9 (2.81)	1.5 (2.27)	1.8 (3.15)
Median	0.5	0.0	0.5	0.0	0.0
Min, Max	0, 14	0, 4	0, 7	0, 7	0, 14

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Number of episodes of schizophrenia					
n	3	7	7	14	17
Mean (SD)	5.0 (0.00)	3.7 (1.70)	3.7 (1.70)	3.7 (1.64)	3.9 (1.56)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	5, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	3	7	7	14	17
1	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
2	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
3	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
4	0	0	0	0	0
5 or more	3 (100.0)	4 (57.1)	4 (57.1)	8 (57.1)	11 (64.7)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	3	7	7	14	17
Mean (SD)	31.3 (6.35)	29.4 (12.18)	30.3 (8.24)	29.9 (10.00)	30.1 (9.31)
Median	35.0	27.0	28.0	28.0	28.0
Min, Max	24, 35	18, 53	21, 43	18, 53	18, 53
Age at the first onset of schizophrenia (years), n (%)					
n	3	7	7	14	17
19 or less	0	2 (28.6)	0	2 (14.3)	2 (11.8)
20 to 29	1 (33.3)	3 (42.9)	5 (71.4)	8 (57.1)	9 (52.9)
30 to 39	2 (66.7)	1 (14.3)	0	1 (7.1)	3 (17.6)
40 to 49	0	0	2 (28.6)	2 (14.3)	2 (11.8)
50 or more	0	1 (14.3)	0	1 (7.1)	1 (5.9)
Unknown	0	0	0	0	0
Duration of illness (years)					
n	3	7	7	14	17
Mean (SD)	19.62 (7.396)	10.50 (5.780)	10.37 (9.413)	10.43 (7.505)	12.05 (8.102)
Median	17.80	10.80	8.40	10.10	10.95
Min, Max	13.3, 27.8	0.6, 17.5	0.5, 27.6	0.5, 27.6	0.5, 27.8
Duration of illness (years), n (%)					
n	3	7	7	14	17

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
<1	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
>=1 to <5	0	0	1 (14.3)	1 (7.1)	1 (5.9)
>=5 to <10	0	2 (28.6)	2 (28.6)	4 (28.6)	4 (23.5)
>=10 to <20	2 (66.7)	4 (57.1)	2 (28.6)	6 (42.9)	8 (47.1)
>=20 to <30	1 (33.3)	0	1 (14.3)	1 (7.1)	2 (11.8)
>=30	0	0	0	0	0
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	3	7	7	14	17
Mean (SD)	1.42 (0.294)	1.10 (0.363)	1.50 (0.675)	1.30 (0.560)	1.32 (0.518)
Median	1.58	1.05	1.77	1.36	1.38
Min, Max	1.1, 1.6	0.6, 1.6	0.3, 2.1	0.3, 2.1	0.3, 2.1
Baseline PANSS total score					
n	3	7	7	14	17
Mean (SD)	99.3 (17.39)	113.4 (17.58)	98.0 (14.55)	105.7 (17.45)	104.6 (17.07)
Median	93.0	119.0	96.0	107.0	99.0
Min, Max	86, 119	84, 133	82, 119	82, 133	82, 133
PANSS composite subscale at baseline, n (%)					
n	3	7	7	14	17
Positive subscale score>Negative subscale score	1 (33.3)	5 (71.4)	4 (57.1)	9 (64.3)	10 (58.8)
Positive subscale score=Negative subscale score	0	0	0	0	0
Positive subscale score<Negative subscale score	2 (66.7)	2 (28.6)	3 (42.9)	5 (35.7)	7 (41.2)
Baseline PANSS total score, n (%)					
n	3	7	7	14	17
<100	2 (66.7)	2 (28.6)	5 (71.4)	7 (50.0)	9 (52.9)
>=100 to <120	1 (33.3)	2 (28.6)	2 (28.6)	4 (28.6)	5 (29.4)
>=120	0	3 (42.9)	0	3 (21.4)	3 (17.6)
Baseline CGI-S score					
n	3	7	7	14	17
Mean (SD)	4.67 (1.155)	5.43 (1.134)	4.43 (0.787)	4.93 (1.072)	4.88 (1.054)

Country: Korea	PLCB-to-FLEX DOSE (N = 3)	40MG-to-FLEX DOSE (N = 7)	80MG-to-FLEX DOSE (N = 7)	Active-to-FLEX DOSE (N = 14)	Overall-to-FLEX DOSE (N = 17)
Median	4.00	6.00	4.00	5.00	5.00
Min, Max	4, 6	3, 6	4, 6	3, 6	3, 6
Baseline CGI-S score, n (%)					
n	3	7	7	14	17
1	0	0	0	0	0
2	0	0	0	0	0
3	0	1 (14.3)	0	1 (7.1)	1 (5.9)
4	2 (66.7)	0	5 (71.4)	5 (35.7)	7 (41.2)
5	0	1 (14.3)	1 (14.3)	2 (14.3)	2 (11.8)
6	1 (33.3)	5 (71.4)	1 (14.3)	6 (42.9)	7 (41.2)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	3	7	7	14	17
Mean (SD)	5.3 (9.24)	0.0 (0.00)	1.1 (2.61)	0.6 (1.87)	1.4 (4.12)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 16	0, 0	0, 7	0, 7	0, 16

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Number of episodes of schizophrenia					
n	43	55	54	109	152
Mean (SD)	3.4 (1.35)	3.5 (1.29)	3.5 (1.44)	3.5 (1.36)	3.5 (1.35)
Median	3.0	3.0	3.5	3.0	3.0
Min, Max	1, 5	1, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	43	58	54	112	155
1	2 (4.7)	2 (3.4)	3 (5.6)	5 (4.5)	7 (4.5)
2	13 (30.2)	13 (22.4)	17 (31.5)	30 (26.8)	43 (27.7)
3	9 (20.9)	14 (24.1)	7 (13.0)	21 (18.8)	30 (19.4)
4	5 (11.6)	7 (12.1)	5 (9.3)	12 (10.7)	17 (11.0)
5 or more	14 (32.6)	19 (32.8)	22 (40.7)	41 (36.6)	55 (35.5)
Unknown	0	3 (5.2)	0	3 (2.7)	3 (1.9)
Age at the first onset of schizophrenia (years)					

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
n	41	56	52	108	149
Mean (SD)	28.1 (8.75)	25.3 (7.03)	25.7 (7.49)	25.5 (7.22)	26.2 (7.73)
Median	27.0	24.0	24.5	24.0	25.0
Min, Max	12, 49	15, 41	13, 55	13, 55	12, 55
Age at the first onset of schizophrenia (years), n (%)					
n	43	58	54	112	155
19 or less	7 (16.3)	11 (19.0)	9 (16.7)	20 (17.9)	27 (17.4)
20 to 29	17 (39.5)	30 (51.7)	30 (55.6)	60 (53.6)	77 (49.7)
30 to 39	14 (32.6)	13 (22.4)	11 (20.4)	24 (21.4)	38 (24.5)
40 to 49	3 (7.0)	2 (3.4)	1 (1.9)	3 (2.7)	6 (3.9)
50 or more	0	0	1 (1.9)	1 (0.9)	1 (0.6)
Unknown	2 (4.7)	2 (3.4)	2 (3.7)	4 (3.6)	6 (3.9)
Duration of illness (years)					
n	41	56	52	108	149
Mean (SD)	12.17 (9.986)	11.39 (9.028)	9.33 (8.674)	10.40 (8.879)	10.89 (9.197)
Median	10.22	9.08	6.08	7.33	8.10
Min, Max	0.1, 40.6	0.0, 32.2	0.0, 38.6	0.0, 38.6	0.0, 40.6
Duration of illness (years), n (%)					
n	43	58	54	112	155
<1	6 (14.0)	5 (8.6)	5 (9.3)	10 (8.9)	16 (10.3)
>=1 to <5	5 (11.6)	13 (22.4)	16 (29.6)	29 (25.9)	34 (21.9)
>=5 to <10	8 (18.6)	10 (17.2)	12 (22.2)	22 (19.6)	30 (19.4)
>=10 to <20	15 (34.9)	18 (31.0)	12 (22.2)	30 (26.8)	45 (29.0)
>=20 to <30	4 (9.3)	8 (13.8)	6 (11.1)	14 (12.5)	18 (11.6)
>=30	3 (7.0)	2 (3.4)	1 (1.9)	3 (2.7)	6 (3.9)
Unknown	2 (4.7)	2 (3.4)	2 (3.7)	4 (3.6)	6 (3.9)
Duration of current episode (months)					
n	43	58	54	112	155
Mean (SD)	1.13 (0.605)	1.23 (1.719)	1.24 (0.615)	1.23 (1.303)	1.20 (1.152)
Median	1.08	0.95	1.13	1.03	1.05
Min, Max	0.2, 2.4	0.2, 13.3	0.2, 2.8	0.2, 13.3	0.2, 13.3
Baseline PANSS total score					
n	43	58	54	112	155
Mean (SD)	97.6 (13.71)	103.2 (15.90)	103.6 (17.35)	103.4 (16.54)	101.8 (15.98)
Median	93.0	101.0	100.0	101.0	100.0

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Min, Max	80, 135	80, 147	82, 168	80, 168	80, 168
PANSS composite subscale at baseline, n (%)					
n	43	58	54	112	155
Positive subscale score>Negative subscale score	26 (60.5)	38 (65.5)	23 (42.6)	61 (54.5)	87 (56.1)
Positive subscale score=Negative subscale score	2 (4.7)	3 (5.2)	2 (3.7)	5 (4.5)	7 (4.5)
Positive subscale score<Negative subscale score	15 (34.9)	17 (29.3)	29 (53.7)	46 (41.1)	61 (39.4)
Baseline PANSS total score, n (%)					
n	43	58	54	112	155
<100	25 (58.1)	25 (43.1)	27 (50.0)	52 (46.4)	77 (49.7)
>=100 to <120	16 (37.2)	23 (39.7)	18 (33.3)	41 (36.6)	57 (36.8)
>=120	2 (4.7)	10 (17.2)	9 (16.7)	19 (17.0)	21 (13.5)
Baseline CGI-S score					
n	43	58	54	112	155
Mean (SD)	4.86 (0.601)	4.91 (0.629)	5.15 (0.529)	5.03 (0.592)	4.98 (0.597)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 6	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	43	58	54	112	155
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	11 (25.6)	14 (24.1)	4 (7.4)	18 (16.1)	29 (18.7)
5	27 (62.8)	35 (60.3)	38 (70.4)	73 (65.2)	100 (64.5)
6	5 (11.6)	9 (15.5)	12 (22.2)	21 (18.8)	26 (16.8)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	43	58	54	112	155
Mean (SD)	0.2 (0.53)	0.3 (1.59)	0.1 (0.56)	0.2 (1.21)	0.2 (1.06)
Median	0.0	0.0	0.0	0.0	0.0

Country: Malaysia	PLCB-to-FLEX DOSE (N = 43)	40MG-to-FLEX DOSE (N = 58)	80MG-to-FLEX DOSE (N = 54)	Active-to-FLEX DOSE (N = 112)	Overall-to-FLEX DOSE (N = 155)
Min, Max	0, 3	0, 10	0, 3	0, 10	0, 10

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Number of episodes of schizophrenia					
n	22	22	22	44	66
Mean (SD)	3.5 (1.22)	3.7 (1.12)	4.0 (1.21)	3.8 (1.16)	3.7 (1.18)
Median	3.0	4.0	4.0	4.0	4.0
Min, Max	2, 5	2, 5	1, 5	1, 5	1, 5
Number of episodes of schizophrenia, n (%)					
n	22	22	22	44	66
1	0	0	1 (4.5)	1 (2.3)	1 (1.5)
2	6 (27.3)	4 (18.2)	2 (9.1)	6 (13.6)	12 (18.2)
3	6 (27.3)	5 (22.7)	4 (18.2)	9 (20.5)	15 (22.7)
4	3 (13.6)	6 (27.3)	5 (22.7)	11 (25.0)	14 (21.2)
5 or more	7 (31.8)	7 (31.8)	10 (45.5)	17 (38.6)	24 (36.4)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	22	22	22	44	66
Mean (SD)	23.7 (7.45)	23.6 (8.23)	22.4 (5.42)	23.0 (6.92)	23.2 (7.05)
Median	21.0	22.0	21.5	22.0	21.5
Min, Max	14, 41	11, 46	13, 35	11, 46	11, 46
Age at the first onset of schizophrenia (years), n (%)					
n	22	22	22	44	66
19 or less	6 (27.3)	8 (36.4)	7 (31.8)	15 (34.1)	21 (31.8)
20 to 29	12 (54.5)	8 (36.4)	12 (54.5)	20 (45.5)	32 (48.5)
30 to 39	3 (13.6)	5 (22.7)	3 (13.6)	8 (18.2)	11 (16.7)
40 to 49	1 (4.5)	1 (4.5)	0	1 (2.3)	2 (3.0)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0
Duration of illness (years)					
n	22	22	22	44	66
Mean (SD)	9.99 (7.262)	8.90 (6.039)	10.05 (9.364)	9.48 (7.808)	9.65 (7.578)
Median	7.88	8.27	7.08	8.27	8.13

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
Min, Max	1.1, 23.1	2.4, 23.6	0.0, 32.4	0.0, 32.4	0.0, 32.4
Duration of illness (years), n (%)					
n	22	22	22	44	66
<1	0	0	2 (9.1)	2 (4.5)	2 (3.0)
>=1 to <5	7 (31.8)	7 (31.8)	7 (31.8)	14 (31.8)	21 (31.8)
>=5 to <10	6 (27.3)	7 (31.8)	5 (22.7)	12 (27.3)	18 (27.3)
>=10 to <20	6 (27.3)	6 (27.3)	4 (18.2)	10 (22.7)	16 (24.2)
>=20 to <30	3 (13.6)	2 (9.1)	3 (13.6)	5 (11.4)	8 (12.1)
>=30	0	0	1 (4.5)	1 (2.3)	1 (1.5)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	22	22	22	44	66
Mean (SD)	1.44 (0.585)	1.32 (0.689)	1.16 (0.637)	1.24 (0.661)	1.31 (0.639)
Median	1.36	1.23	1.10	1.15	1.22
Min, Max	0.4, 2.6	0.4, 3.0	0.4, 2.6	0.4, 3.0	0.4, 3.0
Baseline PANSS total score					
n	22	22	22	44	66
Mean (SD)	98.0 (12.04)	99.0 (15.40)	98.9 (13.12)	98.9 (14.14)	98.6 (13.39)
Median	96.0	93.5	95.0	94.0	94.0
Min, Max	81, 128	83, 138	80, 129	80, 138	80, 138
PANSS composite subscale at baseline, n (%)					
n	22	22	22	44	66
Positive subscale score>Negative subscale score	9 (40.9)	16 (72.7)	11 (50.0)	27 (61.4)	36 (54.5)
Positive subscale score=Negative subscale score	1 (4.5)	0	2 (9.1)	2 (4.5)	3 (4.5)
Positive subscale score<Negative subscale score	12 (54.5)	6 (27.3)	9 (40.9)	15 (34.1)	27 (40.9)
Baseline PANSS total score, n (%)					
n	22	22	22	44	66
<100	12 (54.5)	15 (68.2)	14 (63.6)	29 (65.9)	41 (62.1)
>=100 to <120	8 (36.4)	4 (18.2)	6 (27.3)	10 (22.7)	18 (27.3)

Country: Philippines	PLCB-to-FLEX DOSE (N = 22)	40MG-to-FLEX DOSE (N = 22)	80MG-to-FLEX DOSE (N = 22)	Active-to-FLEX DOSE (N = 44)	Overall-to-FLEX DOSE (N = 66)
>=120	2 (9.1)	3 (13.6)	2 (9.1)	5 (11.4)	7 (10.6)
Baseline CGI-S score					
n	22	22	22	44	66
Mean (SD)	4.82 (0.733)	4.82 (0.853)	4.86 (0.640)	4.84 (0.745)	4.83 (0.736)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 6	4, 7	4, 6	4, 7	4, 7
Baseline CGI-S score, n (%)					
n	22	22	22	44	66
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	8 (36.4)	9 (40.9)	6 (27.3)	15 (34.1)	23 (34.8)
5	10 (45.5)	9 (40.9)	13 (59.1)	22 (50.0)	32 (48.5)
6	4 (18.2)	3 (13.6)	3 (13.6)	6 (13.6)	10 (15.2)
7	0	1 (4.5)	0	1 (2.3)	1 (1.5)
Baseline DIEPSS total score (excluding overall severity)					
n	22	22	22	44	66
Mean (SD)	0.2 (0.61)	0.0 (0.00)	0.2 (0.75)	0.1 (0.54)	0.2 (0.56)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 2	0, 0	0, 3	0, 3	0, 3

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Number of episodes of schizophrenia					
n	10	13	12	25	35
Mean (SD)	4.5 (1.08)	4.5 (0.78)	4.7 (0.65)	4.6 (0.71)	4.6 (0.81)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	2, 5	3, 5	3, 5	3, 5	2, 5
Number of episodes of schizophrenia, n (%)					
n	10	13	12	25	35
1	0	0	0	0	0
2	1 (10.0)	0	0	0	1 (2.9)
3	1 (10.0)	2 (15.4)	1 (8.3)	3 (12.0)	4 (11.4)

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
4	0	2 (15.4)	2 (16.7)	4 (16.0)	4 (11.4)
5 or more	8 (80.0)	9 (69.2)	9 (75.0)	18 (72.0)	26 (74.3)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	10	13	12	25	35
Mean (SD)	23.0 (8.49)	23.2 (7.26)	27.8 (11.55)	25.4 (9.64)	24.7 (9.27)
Median	23.0	23.0	23.5	23.0	23.0
Min, Max	6, 40	8, 32	14, 50	8, 50	6, 50
Age at the first onset of schizophrenia (years), n (%)					
n	10	13	12	25	35
19 or less	2 (20.0)	3 (23.1)	2 (16.7)	5 (20.0)	7 (20.0)
20 to 29	7 (70.0)	7 (53.8)	6 (50.0)	13 (52.0)	20 (57.1)
30 to 39	0	3 (23.1)	2 (16.7)	5 (20.0)	5 (14.3)
40 to 49	1 (10.0)	0	1 (8.3)	1 (4.0)	2 (5.7)
50 or more	0	0	1 (8.3)	1 (4.0)	1 (2.9)
Unknown	0	0	0	0	0
Duration of illness (years)					
n	10	13	12	25	35
Mean (SD)	10.61 (8.062)	16.32 (11.293)	14.82 (8.853)	15.60 (10.013)	14.17 (9.655)
Median	10.03	15.13	14.12	15.13	13.11
Min, Max	0.9, 29.1	2.4, 38.1	3.2, 28.1	2.4, 38.1	0.9, 38.1
Duration of illness (years), n (%)					
n	10	13	12	25	35
<1	2 (20.0)	0	0	0	2 (5.7)
>=1 to <5	0	3 (23.1)	1 (8.3)	4 (16.0)	4 (11.4)
>=5 to <10	3 (30.0)	1 (7.7)	4 (33.3)	5 (20.0)	8 (22.9)
>=10 to <20	4 (40.0)	4 (30.8)	3 (25.0)	7 (28.0)	11 (31.4)
>=20 to <30	1 (10.0)	3 (23.1)	4 (33.3)	7 (28.0)	8 (22.9)
>=30	0	2 (15.4)	0	2 (8.0)	2 (5.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	10	13	12	25	35
Mean (SD)	1.10 (0.517)	1.19 (0.627)	1.53 (0.609)	1.35 (0.629)	1.28 (0.603)
Median	1.25	1.25	1.51	1.48	1.28

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Min, Max	0.2, 1.8	0.3, 2.2	0.3, 2.5	0.3, 2.5	0.2, 2.5
Baseline PANSS total score					
n	10	13	12	25	35
Mean (SD)	100.7 (10.30)	104.7 (20.89)	102.0 (12.63)	103.4 (17.12)	102.6 (15.38)
Median	97.5	99.0	104.0	101.0	99.0
Min, Max	86, 119	87, 146	85, 129	85, 146	85, 146
PANSS composite subscale at baseline, n (%)					
n	10	13	12	25	35
Positive subscale score>Negative subscale score	6 (60.0)	6 (46.2)	6 (50.0)	12 (48.0)	18 (51.4)
Positive subscale score=Negative subscale score	1 (10.0)	1 (7.7)	1 (8.3)	2 (8.0)	3 (8.6)
Positive subscale score<Negative subscale score	3 (30.0)	6 (46.2)	5 (41.7)	11 (44.0)	14 (40.0)
Baseline PANSS total score, n (%)					
n	10	13	12	25	35
<100	6 (60.0)	8 (61.5)	4 (33.3)	12 (48.0)	18 (51.4)
>=100 to <120	4 (40.0)	2 (15.4)	7 (58.3)	9 (36.0)	13 (37.1)
>=120	0	3 (23.1)	1 (8.3)	4 (16.0)	4 (11.4)
Baseline CGI-S score					
n	10	13	12	25	35
Mean (SD)	4.60 (0.516)	4.92 (0.760)	4.67 (0.778)	4.80 (0.764)	4.74 (0.701)
Median	5.00	5.00	4.50	5.00	5.00
Min, Max	4, 5	4, 6	4, 6	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	10	13	12	25	35
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	4 (40.0)	4 (30.8)	6 (50.0)	10 (40.0)	14 (40.0)
5	6 (60.0)	6 (46.2)	4 (33.3)	10 (40.0)	16 (45.7)
6	0	3 (23.1)	2 (16.7)	5 (20.0)	5 (14.3)
7	0	0	0	0	0

Country: Russia	PLCB-to-FLEX DOSE (N = 10)	40MG-to-FLEX DOSE (N = 13)	80MG-to-FLEX DOSE (N = 12)	Active-to-FLEX DOSE (N = 25)	Overall-to-FLEX DOSE (N = 35)
Baseline DIEPSS total score (excluding overall severity)					
n	10	13	12	25	35
Mean (SD)	1.1 (2.28)	1.9 (3.95)	1.3 (2.19)	1.6 (3.17)	1.5 (2.92)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 7	0, 12	0, 7	0, 12	0, 12

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Number of episodes of schizophrenia					
n	5	15	16	31	36
Mean (SD)	2.8 (1.30)	3.1 (1.22)	3.4 (1.36)	3.2 (1.28)	3.2 (1.28)
Median	2.0	3.0	3.5	3.0	3.0
Min, Max	2, 5	2, 5	2, 5	2, 5	2, 5
Number of episodes of schizophrenia, n (%)					
n	5	15	17	32	37
1	0	0	0	0	0
2	3 (60.0)	7 (46.7)	7 (41.2)	14 (43.8)	17 (45.9)
3	1 (20.0)	3 (20.0)	1 (5.9)	4 (12.5)	5 (13.5)
4	0	2 (13.3)	3 (17.6)	5 (15.6)	5 (13.5)
5 or more	1 (20.0)	3 (20.0)	5 (29.4)	8 (25.0)	9 (24.3)
Unknown	0	0	1 (5.9)	1 (3.1)	1 (2.7)
Age at the first onset of schizophrenia (years)					
n	5	15	17	32	37
Mean (SD)	30.6 (7.27)	27.9 (4.82)	29.1 (11.23)	28.5 (8.71)	28.8 (8.47)
Median	32.0	28.0	26.0	27.0	28.0
Min, Max	18, 36	20, 37	17, 60	17, 60	17, 60
Age at the first onset of schizophrenia (years), n (%)					
n	5	15	17	32	37
19 or less	1 (20.0)	0	2 (11.8)	2 (6.3)	3 (8.1)
20 to 29	0	10 (66.7)	10 (58.8)	20 (62.5)	20 (54.1)
30 to 39	4 (80.0)	5 (33.3)	3 (17.6)	8 (25.0)	12 (32.4)
40 to 49	0	0	0	0	0
50 or more	0	0	2 (11.8)	2 (6.3)	2 (5.4)

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Unknown	0	0	0	0	0
Duration of illness (years)					
n	5	15	17	32	37
Mean (SD)	11.37 (10.101)	10.96 (7.899)	14.29 (10.022)	12.73 (9.103)	12.55 (9.106)
Median	10.01	8.00	13.11	10.23	10.09
Min, Max	0.5, 26.4	1.6, 26.6	0.3, 36.3	0.3, 36.3	0.3, 36.3
Duration of illness (years), n (%)					
n	5	15	17	32	37
<1	1 (20.0)	0	2 (11.8)	2 (6.3)	3 (8.1)
>=1 to <5	1 (20.0)	4 (26.7)	2 (11.8)	6 (18.8)	7 (18.9)
>=5 to <10	0	5 (33.3)	2 (11.8)	7 (21.9)	7 (18.9)
>=10 to <20	2 (40.0)	3 (20.0)	7 (41.2)	10 (31.3)	12 (32.4)
>=20 to <30	1 (20.0)	3 (20.0)	3 (17.6)	6 (18.8)	7 (18.9)
>=30	0	0	1 (5.9)	1 (3.1)	1 (2.7)
Unknown	0	0	0	0	0
Duration of current episode (months)					
n	5	15	17	32	37
Mean (SD)	0.83 (0.732)	0.99 (0.407)	0.83 (0.437)	0.90 (0.424)	0.90 (0.464)
Median	0.53	1.02	0.62	0.85	0.79
Min, Max	0.1, 2.0	0.1, 1.6	0.2, 1.8	0.1, 1.8	0.1, 2.0
Baseline PANSS total score					
n	5	15	17	32	37
Mean (SD)	109.8 (20.20)	91.6 (8.42)	93.4 (9.13)	92.6 (8.71)	94.9 (12.10)
Median	108.0	91.0	93.0	92.5	94.0
Min, Max	86, 138	81, 109	80, 113	80, 113	80, 138
PANSS composite subscale at baseline, n (%)					
n	5	15	17	32	37
Positive subscale score>Negative subscale score	3 (60.0)	7 (46.7)	12 (70.6)	19 (59.4)	22 (59.5)
Positive subscale score=Negative subscale score	0	2 (13.3)	0	2 (6.3)	2 (5.4)
Positive subscale score<Negative subscale score	2 (40.0)	6 (40.0)	5 (29.4)	11 (34.4)	13 (35.1)

Country: Taiwan	PLCB-to-FLEX DOSE (N = 5)	40MG-to-FLEX DOSE (N = 15)	80MG-to-FLEX DOSE (N = 17)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 37)
Baseline PANSS total score, n (%)					
n	5	15	17	32	37
<100	2 (40.0)	12 (80.0)	14 (82.4)	26 (81.3)	28 (75.7)
>=100 to <120	1 (20.0)	3 (20.0)	3 (17.6)	6 (18.8)	7 (18.9)
>=120	2 (40.0)	0	0	0	2 (5.4)
Baseline CGI-S score					
n	5	15	17	32	37
Mean (SD)	5.60 (1.140)	4.67 (0.724)	5.12 (0.928)	4.91 (0.856)	5.00 (0.913)
Median	6.00	5.00	5.00	5.00	5.00
Min, Max	4, 7	4, 6	4, 7	4, 7	4, 7
Baseline CGI-S score, n (%)					
n	5	15	17	32	37
1	0	0	0	0	0
2	0	0	0	0	0
3	0	0	0	0	0
4	1 (20.0)	7 (46.7)	5 (29.4)	12 (37.5)	13 (35.1)
5	1 (20.0)	6 (40.0)	6 (35.3)	12 (37.5)	13 (35.1)
6	2 (40.0)	2 (13.3)	5 (29.4)	7 (21.9)	9 (24.3)
7	1 (20.0)	0	1 (5.9)	1 (3.1)	2 (5.4)
Baseline DIEPSS total score (excluding overall severity)					
n	5	15	17	32	37
Mean (SD)	2.2 (4.38)	0.6 (1.12)	1.5 (2.70)	1.1 (2.12)	1.2 (2.48)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 10	0, 4	0, 8	0, 8	0, 10

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Number of episodes of schizophrenia					
n	13	17	15	32	45
Mean (SD)	4.8 (0.60)	4.9 (0.33)	4.9 (0.26)	4.9 (0.30)	4.9 (0.40)
Median	5.0	5.0	5.0	5.0	5.0
Min, Max	3, 5	4, 5	4, 5	4, 5	3, 5

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Number of episodes of schizophrenia, n (%)					
n	13	17	15	32	45
1	0	0	0	0	0
2	0	0	0	0	0
3	1 (7.7)	0	0	0	1 (2.2)
4	1 (7.7)	2 (11.8)	1 (6.7)	3 (9.4)	4 (8.9)
5 or more	11 (84.6)	15 (88.2)	14 (93.3)	29 (90.6)	40 (88.9)
Unknown	0	0	0	0	0
Age at the first onset of schizophrenia (years)					
n	13	17	15	32	45
Mean (SD)	24.5 (6.21)	28.2 (7.70)	24.4 (9.07)	26.4 (8.45)	25.8 (7.85)
Median	22.0	26.0	25.0	25.5	25.0
Min, Max	16, 39	18, 49	8, 47	8, 49	8, 49
Age at the first onset of schizophrenia (years), n (%)					
n	13	17	15	32	45
19 or less	2 (15.4)	1 (5.9)	3 (20.0)	4 (12.5)	6 (13.3)
20 to 29	8 (61.5)	9 (52.9)	9 (60.0)	18 (56.3)	26 (57.8)
30 to 39	3 (23.1)	5 (29.4)	2 (13.3)	7 (21.9)	10 (22.2)
40 to 49	0	2 (11.8)	1 (6.7)	3 (9.4)	3 (6.7)
50 or more	0	0	0	0	0
Unknown	0	0	0	0	0
Duration of illness (years)					
n	13	17	15	32	45
Mean (SD)	14.84 (7.360)	16.38 (9.050)	14.75 (11.610)	15.61 (10.190)	15.39 (9.384)
Median	14.52	16.11	14.11	14.61	14.52
Min, Max	5.0, 27.1	1.8, 33.1	3.1, 44.1	1.8, 44.1	1.8, 44.1
Duration of illness (years), n (%)					
n	13	17	15	32	45
<1	0	0	0	0	0
>=1 to <5	1 (7.7)	1 (5.9)	4 (26.7)	5 (15.6)	6 (13.3)
>=5 to <10	3 (23.1)	5 (29.4)	3 (20.0)	8 (25.0)	11 (24.4)
>=10 to <20	5 (38.5)	6 (35.3)	4 (26.7)	10 (31.3)	15 (33.3)
>=20 to <30	4 (30.8)	4 (23.5)	2 (13.3)	6 (18.8)	10 (22.2)
>=30	0	1 (5.9)	2 (13.3)	3 (9.4)	3 (6.7)
Unknown	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
Duration of current episode (months)					
n	13	17	15	32	45
Mean (SD)	1.34 (0.652)	0.95 (0.651)	0.96 (0.595)	0.96 (0.615)	1.07 (0.644)
Median	1.28	0.62	1.08	0.90	1.08
Min, Max	0.3, 2.5	0.2, 2.2	0.2, 2.2	0.2, 2.2	0.2, 2.5
Baseline PANSS total score					
n	13	17	15	32	45
Mean (SD)	100.8 (8.42)	100.4 (6.17)	101.2 (6.25)	100.8 (6.12)	100.8 (6.76)
Median	104.0	99.0	102.0	100.5	101.0
Min, Max	83, 115	91, 114	88, 114	88, 114	83, 115
PANSS composite subscale at baseline, n (%)					
n	13	17	15	32	45
Positive subscale score>Negative subscale score	7 (53.8)	7 (41.2)	6 (40.0)	13 (40.6)	20 (44.4)
Positive subscale score=Negative subscale score	1 (7.7)	3 (17.6)	0	3 (9.4)	4 (8.9)
Positive subscale score<Negative subscale score	5 (38.5)	7 (41.2)	9 (60.0)	16 (50.0)	21 (46.7)
Baseline PANSS total score, n (%)					
n	13	17	15	32	45
<100	6 (46.2)	9 (52.9)	5 (33.3)	14 (43.8)	20 (44.4)
>=100 to <120	7 (53.8)	8 (47.1)	10 (66.7)	18 (56.3)	25 (55.6)
>=120	0	0	0	0	0
Baseline CGI-S score					
n	13	17	15	32	45
Mean (SD)	4.54 (0.519)	4.65 (0.606)	4.87 (0.352)	4.75 (0.508)	4.69 (0.514)
Median	5.00	5.00	5.00	5.00	5.00
Min, Max	4, 5	4, 6	4, 5	4, 6	4, 6
Baseline CGI-S score, n (%)					
n	13	17	15	32	45
1	0	0	0	0	0

Country: Ukraine	PLCB-to-FLEX DOSE (N = 13)	40MG-to-FLEX DOSE (N = 17)	80MG-to-FLEX DOSE (N = 15)	Active-to-FLEX DOSE (N = 32)	Overall-to-FLEX DOSE (N = 45)
2	0	0	0	0	0
3	0	0	0	0	0
4	6 (46.2)	7 (41.2)	2 (13.3)	9 (28.1)	15 (33.3)
5	7 (53.8)	9 (52.9)	13 (86.7)	22 (68.8)	29 (64.4)
6	0	1 (5.9)	0	1 (3.1)	1 (2.2)
7	0	0	0	0	0
Baseline DIEPSS total score (excluding overall severity)					
n	13	17	15	32	45
Mean (SD)	1.1 (2.06)	0.6 (1.80)	0.5 (0.99)	0.6 (1.46)	0.7 (1.64)
Median	0.0	0.0	0.0	0.0	0.0
Min, Max	0, 7	0, 7	0, 3	0, 7	0, 7

The denominator of percentages is the number of subjects in analysis population of subgroup. Duration of illness is years from the initial episode of schizophrenia to the informed consent. Duration of current episode is months from the onset of current episode to the informed consent. In regard to 'Number of episodes of schizophrenia', a category '5 or more' is set to 5 for descriptive purpose. The final data at Open-Week 52 was used.

表 2.7.3.6-27　治療遵守状況（20 試験：非盲検治療期　Open 24 週）

Open-Label Population

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 143)	80MG-to-FLEX DOSE (N = 157)	Active-to-FLEX DOSE (N = 300)	Overall-to-FLEX DOSE (N = 431)
Treatment compliance (%)					
n	131	143	157	300	431
Mean (SD)	99.1 (4.57)	98.8 (5.04)	99.0 (4.78)	98.9 (4.90)	99.0 (4.79)
Median	100.0	100.0	100.0	100.0	100.0
Min, Max	53, 102	47, 101	50, 100	47, 101	47, 102
Treatment compliance, n (%)					
<80 %	1 (0.8)	2 (1.4)	2 (1.3)	4 (1.3)	5 (1.2)
80 to 120 %	130 (99.2)	141 (98.6)	155 (98.7)	296 (98.7)	426 (98.8)
>120 %	0	0	0	0	0

Compliance (percentage) = (actual number of patches applied/ expected number of patches should have been applied) *100. Expected number of patches = sum of (number of prescribed patches per day *(start date of each prescription period – end date of each prescription period +1)). The data cut-off at Open-Week 24 was used.

表 2.7.3.6-28　曝露状況（20 試験：非盲検治療期　Open 24 週）

Open-Label Population

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 143)	80MG-to-FLEX DOSE (N = 157)	Active-to-FLEX DOSE (N = 300)	Overall-to-FLEX DOSE (N = 431)
Duration of exposure (days)					
n	131	143	157	300	431
Mean (SD)	133.0 (55.42)	130.2 (57.48)	138.2 (52.92)	134.4 (55.19)	134.0 (55.20)
Median	167.0	166.0	167.0	167.0	167.0
Min, Max	2, 175	1, 176	4, 177	1, 177	1, 177
Duration of exposure (weeks), n (%)					
1 to 6	16 (12.2)	25 (17.5)	19 (12.1)	44 (14.7)	60 (13.9)
7 to 12	13 (9.9)	10 (7.0)	13 (8.3)	23 (7.7)	36 (8.4)
13 to 24	71 (54.2)	76 (53.1)	99 (63.1)	175 (58.3)	246 (57.1)
25 to 36	31 (23.7)	32 (22.4)	26 (16.6)	58 (19.3)	89 (20.6)
37 to 48	0	0	0	0	0
49 or more	0	0	0	0	0
Mean daily dose (mg/day)					
n	131	143	157	300	431
Mean (SD)	61.9 (14.35)	60.6 (14.95)	61.9 (14.62)	61.3 (14.77)	61.5 (14.63)
Median	65.2	62.7	65.6	65.0	65.0
Min, Max	40, 78	40, 78	40, 78	40, 78	40, 78
Maximum daily dose, n (%)					
n	131	143	157	300	431
40 mg	24 (18.3)	34 (23.8)	34 (21.7)	68 (22.7)	92 (21.3)
60 mg	26 (19.8)	32 (22.4)	30 (19.1)	62 (20.7)	88 (20.4)
80 mg	81 (61.8)	77 (53.8)	93 (59.2)	170 (56.7)	251 (58.2)
Modal daily dose, n (%)					
n	131	143	157	300	431
40 mg	37 (28.2)	46 (32.2)	46 (29.3)	92 (30.7)	129 (29.9)
60 mg	27 (20.6)	28 (19.6)	27 (17.2)	55 (18.3)	82 (19.0)
80 mg	67 (51.1)	69 (48.3)	84 (53.5)	153 (51.0)	220 (51.0)
Last daily dose (mg/day)					
n	131	143	157	300	431
Mean (SD)	67.0 (16.44)	65.0 (17.03)	65.9 (16.83)	65.5 (16.90)	65.9 (16.76)
Median	80.0	80.0	80.0	80.0	80.0
Min, Max	40, 80	40, 80	40, 80	40, 80	40, 80
Last daily dose, n (%)					
40 mg	29 (22.1)	38 (26.6)	39 (24.8)	77 (25.7)	106 (24.6)
60 mg	27 (20.6)	31 (21.7)	33 (21.0)	64 (21.3)	91 (21.1)

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 143)	80MG-to-FLEX DOSE (N = 157)	Active-to-FLEX DOSE (N = 300)	Overall-to-FLEX DOSE (N = 431)
80 mg	75 (57.3)	74 (51.7)	85 (54.1)	159 (53.0)	234 (54.3)
Cumulative dose (mg)					
n	131	143	157	300	431
Mean (SD)	8308.2 (4037.38)	8059.2 (4206.78)	8720.3 (4016.40)	8405.1 (4114.65)	8375.7 (4086.88)
Median	8540.0	7980.0	9740.0	9140.0	9060.0
Min, Max	80, 13620	40, 13480	160, 13540	40, 13540	40, 13620

Duration of exposure = last dose date – first dose date + 1, during the open-label treatment phase. Duration will not be calculated if either date is missing. Modal daily dose is the most frequently prescribed daily dose during the open-label treatment phase. In the case that two or more dose are the most frequent dose, the maximum of them will be the modal daily dose. The data cut-off at Open-Week 24 was used.

表 2.7.3.6-29　治療遵守状況（20 試験：非盲検治療期　Open 52 週）

Open-Label Population

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 143)	80MG-to-FLEX DOSE (N = 157)	Active-to-FLEX DOSE (N = 300)	Overall-to-FLEX DOSE (N = 431)
Treatment compliance (%)					
n	131	143	157	300	431
Mean (SD)	99.1 (4.56)	98.9 (5.03)	99.1 (4.76)	99.0 (4.88)	99.0 (4.78)
Median	100.0	100.0	100.0	100.0	100.0
Min, Max	53, 102	47, 101	50, 100	47, 101	47, 102
Treatment compliance, n (%)					
<80 %	1 (0.8)	2 (1.4)	2 (1.3)	4 (1.3)	5 (1.2)
80 to 120 %	130 (99.2)	141 (98.6)	155 (98.7)	296 (98.7)	426 (98.8)
>120 %	0	0	0	0	0

Compliance (percentage) = (actual number of patches applied/ expected number of patches should have been applied) *100. Expected number of patches = sum of (number of prescribed patches per day *(start date of each prescription period – end date of each prescription period +1)). The final data at Open-Week 52 was used.

表 2.7.3.6-30　曝露状況（20 試験：非盲検治療期　Open 52 週）

Open-Label Population

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 143)	80MG-to-FLEX DOSE (N = 157)	Active-to-FLEX DOSE (N = 300)	Overall-to-FLEX DOSE (N = 431)
Duration of exposure (days)					
n	131	143	157	300	431
Mean (SD)	169.2 (93.32)	169.6 (99.73)	183.9 (97.14)	177.1 (98.48)	174.7 (96.90)
Median	195.0	195.0	195.0	195.0	195.0
Min, Max	2, 377	1, 377	4, 374	1, 377	1, 377

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 143)	80MG-to-FLEX DOSE (N = 157)	Active-to-FLEX DOSE (N = 300)	Overall-to-FLEX DOSE (N = 431)
Duration of exposure (weeks), n (%)					
1 to 6	16 (12.2)	25 (17.5)	19 (12.1)	44 (14.7)	60 (13.9)
7 to 12	13 (9.9)	10 (7.0)	13 (8.3)	23 (7.7)	36 (8.4)
13 to 24	15 (11.5)	16 (11.2)	11 (7.0)	27 (9.0)	42 (9.7)
25 to 36	72 (55.0)	72 (50.3)	88 (56.1)	160 (53.3)	232 (53.8)
37 to 48	1 (0.8)	3 (2.1)	5 (3.2)	8 (2.7)	9 (2.1)
49 or more	14 (10.7)	17 (11.9)	21 (13.4)	38 (12.7)	52 (12.1)
Mean daily dose (mg/day)					
n	131	143	157	300	431
Mean (SD)	62.1 (14.45)	61.2 (15.19)	62.3 (14.78)	61.8 (14.96)	61.9 (14.79)
Median	66.4	63.8	66.4	65.0	65.2
Min, Max	40, 79	39, 79	40, 79	39, 79	39, 79
Maximum daily dose, n (%)					
n	131	143	157	300	431
40 mg	23 (17.6)	34 (23.8)	32 (20.4)	66 (22.0)	89 (20.6)
60 mg	27 (20.6)	31 (21.7)	32 (20.4)	63 (21.0)	90 (20.9)
80 mg	81 (61.8)	78 (54.5)	93 (59.2)	171 (57.0)	252 (58.5)
Modal daily dose, n (%)					
n	131	143	157	300	431
40 mg	38 (29.0)	41 (28.7)	45 (28.7)	86 (28.7)	124 (28.8)
60 mg	28 (21.4)	31 (21.7)	27 (17.2)	58 (19.3)	86 (20.0)
80 mg	65 (49.6)	71 (49.7)	85 (54.1)	156 (52.0)	221 (51.3)
Last daily dose (mg/day)					
n	131	143	157	300	431
Mean (SD)	66.7 (16.57)	65.3 (16.94)	66.0 (16.71)	65.7 (16.80)	66.0 (16.72)
Median	80.0	80.0	80.0	80.0	80.0
Min, Max	40, 80	40, 80	40, 80	40, 80	40, 80
Last daily dose, n (%)					
40 mg	30 (22.9)	37 (25.9)	38 (24.2)	75 (25.0)	105 (24.4)
60 mg	27 (20.6)	31 (21.7)	34 (21.7)	65 (21.7)	92 (21.3)
80 mg	74 (56.5)	75 (52.4)	85 (54.1)	160 (53.3)	234 (54.3)
Cumulative dose (mg)					
n	131	143	157	300	431
Mean (SD)	10606.7 (6457.73)	10810.3 (7587.53)	11672.1 (6809.28)	11261.3 (7191.54)	11062.4 (6975.72)

	PLCB-to-FLEX DOSE (N = 131)	40MG-to-FLEX DOSE (N = 143)	80MG-to-FLEX DOSE (N = 157)	Active-to-FLEX DOSE (N = 300)	Overall-to-FLEX DOSE (N = 431)
Median	10640.0	9040.0	12180.0	11250.0	11220.0
Min, Max	80, 29260	40, 29660	160, 29500	40, 29660	40, 29660

Duration of exposure = last dose date – first dose date + 1, during the open-label treatment phase. Duration will not be calculated if either date is missing. Modal daily dose is the most frequently prescribed daily dose during the open-label treatment phase, In the case that two or more dose are the most frequent dose, the maximum of them will be the modal daily dose. The final data at Open-Week 52 was used.

表 2.7.3.6-31　PANSS 合計スコア変化量
（20 試験：ロナセンテープ貼付期　Open 52 週）

DSP-5423P Dosed Population

		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	84.6 (19.98)		101.6 (15.55)		101.5 (14.69)		101.6 (15.11)		97.3 (18.02)	
	Median	85.0		99.0		99.0		99.0		97.0	
	Min, Max	38, 148		80, 157		80, 168		80, 168		38, 168	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	80.9 (20.19)	-3.4 (7.56)	95.7 (18.16)	-5.9 (10.51)	94.0 (17.12)	-7.5 (12.36)	94.9 (17.65)	-6.7 (11.48)	91.4 (19.27)	-5.9 (10.72)
	Median	79.0	-2.0	94.0	-4.5	92.5	-6.0	93.0	-5.0	91.0	-4.0
	Min, Max	37, 144	-40, 18	45, 154	-41, 36	56, 168	-71, 36	45, 168	-71, 36	37, 168	-71, 36
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	78.1 (19.64)	-6.4 (10.85)	89.4 (19.21)	-11.7 (14.20)	87.5 (18.38)	-14.1 (16.23)	88.5 (18.80)	-12.9 (15.29)	85.7 (19.55)	-11.2 (14.53)
	Median	75.0	-6.0	89.0	-11.0	88.0	-11.0	88.0	-11.0	85.0	-9.0
	Min, Max	38, 141	-39, 21	36, 162	-50, 42	36, 167	-105, 23	36, 167	-105, 42	36, 167	-105, 42
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	75.4 (19.59)	-9.2 (13.31)	83.8 (18.67)	-17.0 (14.75)	81.6 (19.43)	-20.0 (18.20)	82.7 (19.06)	-18.5 (16.64)	80.7 (19.46)	-16.0 (16.34)
	Median	74.0	-8.0	83.0	-16.0	83.0	-16.5	83.0	-16.0	80.5	-14.0
	Min, Max	38, 129	-55, 37	34, 147	-63, 21	38, 146	-105, 17	34, 147	-105, 21	34, 147	-105, 37

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	PLCB-to-FLEX DOSE (N = 131) Change	40MG-to-FLEX DOSE (N = 196) Observed	40MG-to-FLEX DOSE (N = 196) Change	80MG-to-FLEX DOSE (N = 194) Observed	80MG-to-FLEX DOSE (N = 194) Change	Active-to-FLEX DOSE (N = 390) Observed	Active-to-FLEX DOSE (N = 390) Change	Overall-to-FLEX DOSE (N = 521) Observed	Overall-to-FLEX DOSE (N = 521) Change
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			80.9 (18.86)	-19.3 (16.75)	78.7 (20.74)	-22.7 (20.18)	79.8 (19.85)	-21.0 (18.65)	79.8 (19.85)	-21.0 (18.65)
	Median			80.5	-18.0	81.0	-19.0	81.0	-18.0	81.0	-18.0
	Min, Max			34, 146	-73, 14	34, 136	-115, 12	34, 146	-115, 14	34, 146	-115, 14
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			77.1 (19.53)	-23.5 (17.52)	77.2 (20.98)	-24.3 (20.99)	77.2 (20.27)	-23.9 (19.38)	77.2 (20.27)	-23.9 (19.38)
	Median			76.0	-23.5	79.0	-20.0	77.0	-21.5	77.0	-21.5
	Min, Max			32, 150	-77, 21	32, 139	-115, 24	32, 150	-115, 24	32, 150	-115, 24
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	71.9 (21.56)	-12.7 (18.70)	75.9 (20.26)	-24.7 (18.37)	74.9 (20.27)	-26.6 (21.28)	75.4 (20.24)	-25.7 (19.95)	74.4 (20.66)	-22.0 (20.45)
	Median	70.0	-11.0	72.0	-24.0	76.5	-22.0	74.0	-24.0	73.0	-20.0
	Min, Max	34, 133	-66, 53	34, 161	-77, 19	30, 130	-115, 15	30, 161	-115, 19	30, 161	-115, 53
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			74.0 (20.44)	-26.7 (19.23)	72.5 (20.43)	-29.2 (21.71)	73.2 (20.41)	-28.0 (20.56)	73.2 (20.41)	-28.0 (20.56)
	Median			69.0	-26.0	72.5	-25.5	71.0	-26.0	71.0	-26.0
	Min, Max			32, 167	-94, 21	30, 122	-115, 18	30, 167	-115, 21	30, 167	-115, 21

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
		Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	68.7 (20.38)	-15.3 (18.58)							68.7 (20.38)	-15.3 (18.58)
	Median	66.0	-10.0							66.0	-10.0
	Min, Max	32, 137	-66, 33							32, 137	-66, 33
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			71.3 (21.13)	-29.0 (21.16)	70.8 (19.98)	-30.4 (20.97)	71.0 (20.49)	-29.7 (21.03)	71.0 (20.49)	-29.7 (21.03)
	Median			69.0	-28.0	71.0	-28.5	70.0	-28.0	70.0	-28.0
	Min, Max			30, 158	-107, 32	30, 121	-116, 10	30, 158	-116, 32	30, 158	-116, 32
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	66.0 (18.46)	-17.6 (18.26)							66.0 (18.46)	-17.6 (18.26)
	Median	63.0	-15.0							63.0	-15.0
	Min, Max	31, 122	-64, 23							31, 122	-64, 23
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			65.9 (17.83)	-34.0 (18.93)	67.5 (19.03)	-33.4 (21.30)	66.7 (18.46)	-33.7 (20.19)	66.7 (18.46)	-33.7 (20.19)
	Median			64.0	-35.0	67.0	-31.0	66.0	-32.0	66.0	-32.0
	Min, Max			30, 106	-99, 7	30, 111	-116, 11	30, 111	-116, 11	30, 111	-116, 11
On-treatment Week 20	n	90	90							90	90

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	PLCB-to-FLEX DOSE (N = 131) Change	40MG-to-FLEX DOSE (N = 196) Observed	40MG-to-FLEX DOSE (N = 196) Change	80MG-to-FLEX DOSE (N = 194) Observed	80MG-to-FLEX DOSE (N = 194) Change	Active-to-FLEX DOSE (N = 390) Observed	Active-to-FLEX DOSE (N = 390) Change	Overall-to-FLEX DOSE (N = 521) Observed	Overall-to-FLEX DOSE (N = 521) Change
	Mean (SD)	65.1 (20.33)	-18.9 (21.14)							65.1 (20.33)	-18.9 (21.14)
	Median	63.0	-18.0							63.0	-18.0
	Min, Max	32, 130	-71, 47							32, 130	-71, 47
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			64.0 (17.57)	-35.3 (18.99)	66.1 (19.26)	-34.9 (21.31)	65.2 (18.48)	-35.1 (20.22)	65.2 (18.48)	-35.1 (20.22)
	Median			65.0	-36.0	65.0	-32.0	65.0	-34.0	65.0	-34.0
	Min, Max			30, 105	-93, 14	32, 110	-117, 3	30, 110	-117, 14	30, 110	-117, 14
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	63.4 (20.69)	-20.9 (20.52)							63.4 (20.69)	-20.9 (20.52)
	Median	63.0	-18.0							63.0	-18.0
	Min, Max	31, 130	-69, 32							31, 130	-69, 32
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			62.2 (18.88)	-38.0 (19.40)	64.6 (20.85)	-36.6 (22.34)	63.5 (19.96)	-37.2 (21.01)	63.5 (19.96)	-37.2 (21.01)
	Median			59.0	-40.0	64.0	-34.0	61.5	-37.0	61.5	-37.0
	Min, Max			30, 114	-99, 6	31, 118	-118, 20	30, 118	-118, 20	30, 118	-118, 20
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	62.1 (21.04)	-23.1 (20.73)							62.1 (21.04)	-23.1 (20.73)
	Median	60.0	-21.0							60.0	-21.0

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
		Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	34, 130	-73, 20							34, 130	-73, 20
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			59.6 (17.67)	-39.5 (19.24)	63.5 (20.93)	-37.8 (23.01)	61.8 (19.58)	-38.6 (21.37)	61.8 (19.58)	-38.6 (21.37)
	Median			58.5	-41.0	64.0	-36.0	61.0	-37.0	61.0	-37.0
	Min, Max			30, 108	-103, 6	30, 125	-118, 34	30, 125	-118, 34	30, 125	-118, 34
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			59.3 (17.81)	-39.9 (19.60)	60.8 (20.06)	-40.5 (21.59)	60.1 (19.06)	-40.2 (20.68)	60.1 (19.06)	-40.2 (20.68)
	Median			59.0	-41.0	60.0	-38.5	60.0	-39.0	60.0	-39.0
	Min, Max			30, 112	-96, 10	30, 117	-118, 10	30, 117	-118, 10	30, 117	-118, 10
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	78.8 (25.16)	-12.9 (22.57)							78.8 (25.16)	-12.9 (22.57)
	Median	85.0	-11.0							85.0	-11.0
	Min, Max	36, 133	-67, 23							36, 133	-67, 23
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			75.8 (18.50)	-28.5 (24.49)	79.0 (20.21)	-27.1 (23.84)	77.6 (19.36)	-27.7 (23.86)	77.6 (19.36)	-27.7 (23.86)
	Median			73.5	-26.0	76.0	-27.0	75.0	-27.0	75.0	-27.0
	Min, Max			34, 112	-94, 10	31, 111	-118, 2	31, 112	-118, 10	31, 112	-118, 10

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
		Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	73.4 (21.19)	-16.6 (22.42)							73.4 (21.19)	-16.6 (22.42)
	Median	74.0	-11.0							74.0	-11.0
	Min, Max	35, 100	-72, 8							35, 100	-72, 8
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			76.5 (19.86)	-27.8 (25.71)	79.4 (21.83)	-26.2 (24.97)	78.1 (20.79)	-26.9 (25.02)	78.1 (20.79)	-26.9 (25.02)
	Median			73.0	-25.5	77.0	-21.0	75.0	-24.0	75.0	-24.0
	Min, Max			35, 120	-90, 18	31, 121	-118, 4	31, 121	-118, 18	31, 121	-118, 18
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	72.8 (23.42)	-17.5 (24.94)							72.8 (23.42)	-17.5 (24.94)
	Median	77.0	-10.0							77.0	-10.0
	Min, Max	35, 103	-72, 11							35, 103	-72, 11
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			71.4 (19.90)	-33.9 (27.78)	76.5 (20.57)	-29.2 (24.88)	74.2 (20.18)	-31.3 (25.93)	74.2 (20.18)	-31.3 (25.93)
	Median			73.0	-31.0	74.5	-27.5	74.0	-29.0	74.0	-29.0
	Min, Max			33, 105	-102, 9	31, 114	-118, 1	31, 114	-118, 9	31, 114	-118, 9
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	Change	40MG-to-FLEX DOSE (N = 196) Observed	Change	80MG-to-FLEX DOSE (N = 194) Observed	Change	Active-to-FLEX DOSE (N = 390) Observed	Change	Overall-to-FLEX DOSE (N = 521) Observed	Change
	Mean (SD)	69.8 (25.57)	-14.6 (24.28)	78.8 (28.63)	-22.8 (26.29)	72.7 (25.92)	-28.8 (26.37)	75.8 (27.46)	-25.8 (26.47)	74.3 (27.10)	-23.0 (26.36)
	Median	65.5	-12.5	75.5	-22.0	69.0	-30.0	72.0	-25.0	70.0	-22.0
	Min, Max	31, 137	-73, 53	30, 167	-102, 42	30, 136	-118, 36	30, 167	-118, 42	30, 167	-118, 53

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline value are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-32　PANSS 合計スコア変化量
（20 試験：非盲検治療期　Open 52 週）

Open-Label Population

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	Change	40MG-to-FLEX DOSE (N = 143) Observed	Change	80MG-to-FLEX DOSE (N = 157) Observed	Change	Active-to-FLEX DOSE (N = 300) Observed	Change
Baseline	n	131		143		157		300	
	Mean (SD)	84.6 (19.98)		80.1 (19.23)		78.1 (20.28)		79.1 (19.78)	
	Median	85.0		79.0		81.0		80.0	
	Min, Max	38, 148		34, 146		34, 135		34, 146	
Open-Week 1	n	129	129	142	142	156	156	298	298
	Mean (SD)	80.9 (20.19)	-3.4 (7.56)	77.1 (19.53)	-3.1 (7.58)	77.2 (20.98)	-1.0 (8.79)	77.2 (20.27)	-2.0 (8.29)
	Median	79.0	-2.0	76.0	-2.5	79.0	-1.0	77.0	-2.0
	Min, Max	37, 144	-40, 18	32, 150	-47, 26	32, 139	-28, 62	32, 150	-47, 62
Open-Week 2	n	129	129	137	137	154	154	291	291
	Mean (SD)	78.1 (19.64)	-6.4 (10.85)	75.9 (20.26)	-4.2 (9.89)	74.9 (20.27)	-3.6 (9.38)	75.4 (20.24)	-3.9 (9.61)

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	Change	40MG-to-FLEX DOSE (N = 143) Observed	Change	80MG-to-FLEX DOSE (N = 157) Observed	Change	Active-to-FLEX DOSE (N = 300) Observed	Change
	Median	75.0	-6.0	72.0	-4.0	76.5	-4.0	74.0	-4.0
	Min, Max	38, 141	-39, 21	34, 161	-42, 33	30, 130	-34, 42	30, 161	-42, 42
Open-Week 4	n	125	125	134	134	146	146	280	280
	Mean (SD)	75.4 (19.59)	-9.2 (13.31)	74.0 (20.44)	-5.8 (10.90)	72.5 (20.43)	-5.8 (11.59)	73.2 (20.41)	-5.8 (11.24)
	Median	74.0	-8.0	69.0	-5.0	72.5	-6.0	71.0	-6.0
	Min, Max	38, 129	-55, 37	32, 167	-47, 29	30, 122	-52, 52	30, 167	-52, 52
Open-Week 8	n	117	117	127	127	142	142	269	269
	Mean (SD)	71.9 (21.56)	-12.7 (18.70)	71.3 (21.13)	-7.6 (13.33)	70.8 (19.98)	-7.6 (11.87)	71.0 (20.49)	-7.6 (12.55)
	Median	70.0	-11.0	69.0	-6.0	71.0	-7.5	70.0	-7.0
	Min, Max	34, 133	-66, 53	30, 158	-47, 50	30, 121	-43, 19	30, 158	-47, 50
Open-Week 12	n	104	104	109	109	126	126	235	235
	Mean (SD)	68.7 (20.38)	-15.3 (18.58)	65.9 (17.83)	-11.8 (13.55)	67.5 (19.03)	-10.3 (12.88)	66.7 (18.46)	-11.0 (13.19)
	Median	66.0	-10.0	64.0	-12.0	67.0	-9.0	66.0	-9.0
	Min, Max	32, 137	-66, 33	30, 106	-46, 43	30, 111	-42, 26	30, 111	-46, 43
Open-Week 16	n	99	99	107	107	122	122	229	229
	Mean (SD)	66.0 (18.46)	-17.6 (18.26)	64.0 (17.57)	-13.1 (15.69)	66.1 (19.26)	-11.9 (13.70)	65.2 (18.48)	-12.5 (14.65)
	Median	63.0	-15.0	65.0	-12.0	65.0	-11.0	65.0	-11.0
	Min, Max	31, 122	-64, 23	30, 105	-57, 50	32, 110	-47, 19	30, 110	-57, 50
Open-Week 20	n	90	90	99	99	117	117	216	216
	Mean (SD)	65.1 (20.33)	-18.9 (21.14)	62.2 (18.88)	-15.6 (16.18)	64.6 (20.85)	-13.3 (13.64)	63.5 (19.96)	-14.4 (14.86)

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	Change	40MG-to-FLEX DOSE (N = 143) Observed	Change	80MG-to-FLEX DOSE (N = 157) Observed	Change	Active-to-FLEX DOSE (N = 300) Observed	Change
	Median	63.0	-18.0	59.0	-15.0	64.0	-14.0	61.5	-14.0
	Min, Max	32, 130	-71, 47	30, 114	-62, 25	31, 118	-44, 24	30, 118	-62, 25
Open-Week 24	n	89	89	92	92	113	113	205	205
	Mean (SD)	63.4 (20.69)	-20.9 (20.52)	59.6 (17.67)	-17.8 (15.46)	63.5 (20.93)	-14.5 (14.43)	61.8 (19.58)	-16.0 (14.95)
	Median	63.0	-18.0	58.5	-16.5	64.0	-14.0	61.0	-16.0
	Min, Max	31, 130	-69, 32	30, 108	-62, 9	30, 125	-48, 33	30, 125	-62, 33
Open-Week 28	n	83	83	91	91	114	114	205	205
	Mean (SD)	62.1 (21.04)	-23.1 (20.73)	59.3 (17.81)	-18.5 (16.09)	60.8 (20.06)	-17.0 (14.10)	60.1 (19.06)	-17.6 (14.99)
	Median	60.0	-21.0	59.0	-16.0	60.0	-17.0	60.0	-17.0
	Min, Max	34, 130	-73, 20	30, 112	-57, 10	30, 117	-54, 14	30, 117	-57, 14
Open-Week 36	n	17	17	20	20	27	27	47	47
	Mean (SD)	78.8 (25.16)	-12.9 (22.57)	75.8 (18.50)	-12.7 (18.21)	79.0 (20.21)	-9.0 (10.68)	77.6 (19.36)	-10.6 (14.31)
	Median	85.0	-11.0	73.5	-8.5	76.0	-9.0	75.0	-9.0
	Min, Max	36, 133	-67, 23	34, 112	-57, 11	31, 111	-33, 13	31, 112	-57, 13
Open-Week 44	n	15	15	20	20	25	25	45	45
	Mean (SD)	73.4 (21.19)	-16.6 (22.42)	76.5 (19.86)	-12.1 (20.29)	79.4 (21.83)	-7.6 (9.90)	78.1 (20.79)	-9.6 (15.37)
	Median	74.0	-11.0	73.0	-9.5	77.0	-8.0	75.0	-9.0
	Min, Max	35, 100	-72, 8	35, 120	-57, 24	31, 121	-25, 10	31, 121	-57, 24
Open-Week 52	n	13	13	17	17	22	22	39	39
	Mean (SD)	72.8 (23.42)	-17.5 (24.94)	71.4 (19.90)	-16.2 (21.26)	76.5 (20.57)	-9.0 (10.49)	74.2 (20.18)	-12.1 (16.25)

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	Change	40MG-to-FLEX DOSE (N = 143) Observed	Change	80MG-to-FLEX DOSE (N = 157) Observed	Change	Active-to-FLEX DOSE (N = 300) Observed	Change
	Median	77.0	-10.0	73.0	-11.0	74.5	-8.5	74.0	-9.0
	Min, Max	35, 103	-72, 11	33, 105	-57, 27	31, 114	-25, 9	31, 114	-57, 27
Open-Week (LOCF)	n	130	130	143	143	157	157	300	300
	Mean (SD)	69.8 (25.57)	-14.6 (24.28)	69.0 (24.21)	-11.1 (19.49)	67.0 (23.21)	-11.2 (17.96)	67.9 (23.67)	-11.1 (18.67)
	Median	65.5	-12.5	67.0	-9.0	64.0	-11.0	65.0	-10.0
	Min, Max	31, 137	-73, 53	30, 167	-57, 50	30, 125	-54, 62	30, 167	-57, 62

表 2.7.3.6-33　PANSS サブスケール別合計スコア変化量
（20 試験：ロナセンテープ貼付期　Open 52 週）

DSP-5423P Dosed Population

Positive subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	20.3 (6.62)		26.3 (4.81)		25.7 (4.92)		26.0 (4.87)		24.6 (5.89)	
	Median	20.0		26.0		25.5		26.0		25.0	
	Min, Max	7, 43		13, 44		14, 43		13, 44		7, 44	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	19.4 (6.57)	-0.9 (2.97)	24.2 (5.89)	-2.1 (3.85)	23.2 (5.39)	-2.5 (3.75)	23.7 (5.67)	-2.3 (3.80)	22.6 (6.19)	-1.9 (3.66)
	Median	19.0	-1.0	23.5	-2.0	23.0	-2.0	23.0	-2.0	22.0	-1.0
	Min, Max	7, 39	-11, 7	11, 44	-13, 14	10, 43	-21, 9	10, 44	-21, 14	7, 44	-21, 14

Positive subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	18.4 (6.40)	-1.8 (3.95)	22.4 (6.32)	-3.7 (5.09)	21.0 (5.47)	-4.6 (4.87)	21.7 (5.94)	-4.2 (4.99)	20.9 (6.23)	-3.5 (4.85)
	Median	18.0	-2.0	22.0	-4.0	21.0	-4.0	21.0	-4.0	21.0	-3.0
	Min, Max	7, 38	-12, 7	8, 42	-18, 17	7, 43	-25, 7	7, 43	-25, 17	7, 43	-25, 17
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	17.7 (6.47)	-2.6 (5.46)	20.7 (6.26)	-5.4 (4.98)	19.1 (5.77)	-6.5 (5.73)	19.9 (6.05)	-6.0 (5.40)	19.3 (6.24)	-5.1 (5.61)
	Median	17.0	-2.0	20.0	-5.0	19.0	-6.0	19.0	-6.0	19.0	-5.0
	Min, Max	7, 36	-16, 18	7, 40	-20, 10	8, 37	-27, 7	7, 40	-27, 10	7, 40	-27, 18
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			19.7 (6.02)	-6.1 (5.48)	18.3 (6.10)	-7.3 (6.38)	19.0 (6.10)	-6.7 (5.98)	19.0 (6.10)	-6.7 (5.98)
	Median			19.0	-6.0	18.0	-6.5	19.0	-6.0	19.0	-6.0
	Min, Max			8, 35	-18, 9	7, 37	-31, 5	7, 37	-31, 9	7, 37	-31, 9
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			18.4 (5.87)	-7.5 (5.63)	18.1 (6.70)	-7.4 (7.09)	18.3 (6.31)	-7.5 (6.42)	18.3 (6.31)	-7.5 (6.42)
	Median			18.0	-7.0	18.0	-7.0	18.0	-7.0	18.0	-7.0
	Min, Max			7, 36	-23, 11	7, 41	-31, 12	7, 41	-31, 12	7, 41	-31, 12

Positive subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	16.4 (6.63)	-3.9 (6.42)	17.9 (6.29)	-7.9 (6.20)	17.4 (6.20)	-8.2 (6.76)	17.6 (6.24)	-8.1 (6.49)	17.3 (6.37)	-6.9 (6.74)
	Median	16.0	-3.0	17.0	-8.0	17.0	-7.0	17.0	-7.0	16.5	-6.0
	Min, Max	7, 38	-20, 22	7, 36	-22, 9	7, 36	-31, 6	7, 36	-31, 9	7, 38	-31, 22
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			17.3 (6.17)	-8.5 (6.36)	16.8 (6.35)	-8.8 (7.04)	17.0 (6.26)	-8.7 (6.71)	17.0 (6.26)	-8.7 (6.71)
	Median			16.5	-8.0	16.0	-8.0	16.0	-8.0	16.0	-8.0
	Min, Max			7, 37	-24, 6	7, 37	-31, 9	7, 37	-31, 9	7, 37	-31, 9
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	15.4 (6.13)	-4.6 (6.49)							15.4 (6.13)	-4.6 (6.49)
	Median	14.0	-4.0							14.0	-4.0
	Min, Max	7, 38	-23, 10							7, 38	-23, 10
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			16.5 (6.68)	-9.2 (7.04)	16.3 (6.37)	-9.3 (6.97)	16.4 (6.51)	-9.3 (6.99)	16.4 (6.51)	-9.3 (6.99)
	Median			15.0	-9.0	16.0	-9.0	16.0	-9.0	16.0	-9.0
	Min, Max			7, 46	-26, 18	7, 41	-33, 11	7, 46	-33, 18	7, 46	-33, 18
On-treatment Week 16	n	99	99							99	99

Positive subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	14.5 (5.91)	-5.5 (6.94)							14.5 (5.91)	-5.5 (6.94)
	Median	14.0	-5.0							14.0	-5.0
	Min, Max	7, 39	-23, 10							7, 39	-23, 10
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			14.4 (4.93)	-11.1 (5.90)	14.9 (5.04)	-10.5 (6.74)	14.7 (4.98)	-10.7 (6.36)	14.7 (4.98)	-10.7 (6.36)
	Median			14.0	-12.0	14.5	-9.5	14.0	-10.0	14.0	-10.0
	Min, Max			7, 27	-26, 1	7, 30	-31, 6	7, 30	-31, 6	7, 30	-31, 6
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	14.3 (6.27)	-5.8 (7.35)							14.3 (6.27)	-5.8 (7.35)
	Median	13.0	-6.0							13.0	-6.0
	Min, Max	7, 39	-23, 18							7, 39	-23, 18
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			13.9 (5.20)	-11.5 (6.21)	14.6 (5.41)	-10.8 (6.87)	14.3 (5.31)	-11.1 (6.57)	14.3 (5.31)	-11.1 (6.57)
	Median			13.0	-12.0	14.0	-10.0	14.0	-11.0	14.0	-11.0
	Min, Max			7, 27	-26, 4	7, 30	-33, 6	7, 30	-33, 6	7, 30	-33, 6
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	13.8 (6.11)	-6.5 (7.09)							13.8 (6.11)	-6.5 (7.09)
	Median	13.0	-6.0							13.0	-6.0

Positive subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	7, 39	-23, 10							7, 39	-23, 10
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			13.5 (5.31)	-12.2 (6.34)	14.0 (5.65)	-11.5 (7.17)	13.8 (5.49)	-11.8 (6.79)	13.8 (5.49)	-11.8 (6.79)
	Median			12.0	-13.0	13.0	-12.0	13.0	-12.0	13.0	-12.0
	Min, Max			7, 28	-26, 6	7, 37	-33, 9	7, 37	-33, 9	7, 37	-33, 9
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	13.7 (6.36)	-6.7 (7.16)							13.7 (6.36)	-6.7 (7.16)
	Median	12.0	-7.0							12.0	-7.0
	Min, Max	7, 39	-23, 9							7, 39	-23, 9
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			12.9 (4.80)	-12.5 (6.30)	13.7 (5.61)	-11.8 (7.25)	13.4 (5.27)	-12.1 (6.84)	13.4 (5.27)	-12.1 (6.84)
	Median			12.0	-12.0	13.0	-12.0	13.0	-12.0	13.0	-12.0
	Min, Max			7, 30	-26, 8	7, 37	-33, 8	7, 37	-33, 8	7, 37	-33, 8
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			12.7 (4.63)	-12.7 (6.39)	13.1 (5.29)	-12.5 (6.91)	12.9 (5.00)	-12.6 (6.67)	12.9 (5.00)	-12.6 (6.67)
	Median			11.0	-12.0	12.0	-12.0	12.0	-12.0	12.0	-12.0
	Min, Max			7, 30	-26, 8	7, 37	-33, 7	7, 37	-33, 8	7, 37	-33, 8

Positive subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	18.0 (9.56)	-2.5 (7.52)							18.0 (9.56)	-2.5 (7.52)
	Median	17.0	-3.0							17.0	-3.0
	Min, Max	7, 48	-17, 16							7, 48	-17, 16
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			16.2 (5.38)	-8.1 (7.69)	17.0 (5.58)	-6.8 (5.48)	16.6 (5.45)	-7.3 (6.46)	16.6 (5.45)	-7.3 (6.46)
	Median			16.0	-7.5	16.0	-6.0	16.0	-7.0	16.0	-7.0
	Min, Max			8, 29	-24, 7	7, 28	-16, 3	7, 29	-24, 7	7, 29	-24, 7
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	15.1 (5.10)	-4.3 (6.08)							15.1 (5.10)	-4.3 (6.08)
	Median	15.0	-3.0							15.0	-3.0
	Min, Max	7, 23	-19, 4							7, 23	-19, 4
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			16.3 (5.86)	-8.0 (8.27)	17.6 (6.45)	-6.2 (6.21)	17.0 (6.16)	-7.0 (7.17)	17.0 (6.16)	-7.0 (7.17)
	Median			16.5	-8.0	18.0	-6.0	17.0	-6.0	17.0	-6.0
	Min, Max			7, 31	-25, 9	7, 32	-17, 5	7, 32	-25, 9	7, 32	-25, 9
On-treatment Week 52	n	13	13							13	13

Positive subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	15.5 (5.74)	-4.5 (6.45)							15.5 (5.74)	-4.5 (6.45)
	Median	15.0	-2.0							15.0	-2.0
	Min, Max	7, 25	-19, 4							7, 25	-19, 4
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			15.2 (5.39)	-9.6 (8.01)	16.7 (5.23)	-6.9 (4.96)	16.0 (5.28)	-8.1 (6.51)	16.0 (5.28)	-8.1 (6.51)
	Median			17.0	-8.0	17.5	-6.0	17.0	-7.0	17.0	-7.0
	Min, Max			8, 27	-26, 2	7, 28	-16, 3	7, 28	-26, 3	7, 28	-26, 3
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	16.2 (8.14)	-4.0 (8.37)	19.3 (9.14)	-7.0 (8.72)	17.0 (8.01)	-8.7 (8.31)	18.1 (8.67)	-7.8 (8.56)	17.7 (8.57)	-6.9 (8.66)
	Median	14.0	-3.0	18.5	-7.0	15.0	-9.0	17.0	-8.0	16.0	-7.0
	Min, Max	7, 48	-23, 22	7, 46	-26, 18	7, 41	-33, 11	7, 46	-33, 18	7, 48	-33, 22

Negative subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	23.1 (5.93)		25.4 (5.70)		26.3 (5.55)		25.9 (5.64)		25.2 (5.83)	
	Median	23.0		25.0		26.0		25.0		25.0	
	Min, Max	8, 41		13, 43		13, 46		13, 46		8, 46	

Negative subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	21.9 (5.80)	-1.0 (2.41)	24.5 (5.95)	-1.0 (2.59)	24.7 (5.78)	-1.5 (3.30)	24.6 (5.86)	-1.2 (2.97)	23.9 (5.95)	-1.2 (2.84)
	Median	22.0	0.0	24.0	-0.5	25.0	-1.0	24.0	-1.0	24.0	0.0
	Min, Max	9, 41	-11, 5	14, 43	-9, 12	11, 46	-21, 9	11, 46	-21, 12	9, 46	-21, 12
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	21.4 (5.98)	-1.7 (3.28)	23.0 (5.87)	-2.3 (3.43)	23.3 (6.04)	-3.1 (4.71)	23.1 (5.95)	-2.7 (4.14)	22.7 (6.00)	-2.4 (3.95)
	Median	21.0	-1.0	22.0	-2.0	24.0	-2.0	23.0	-2.0	23.0	-2.0
	Min, Max	9, 39	-12, 8	10, 43	-13, 8	9, 45	-31, 9	9, 45	-31, 9	9, 45	-31, 9
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	20.4 (5.66)	-2.6 (3.60)	22.0 (5.83)	-3.3 (4.07)	22.3 (6.04)	-4.1 (5.02)	22.1 (5.93)	-3.7 (4.59)	21.7 (5.90)	-3.4 (4.37)
	Median	20.0	-2.0	22.0	-3.0	22.0	-3.0	22.0	-3.0	21.0	-3.0
	Min, Max	9, 38	-16, 7	9, 43	-15, 6	8, 42	-29, 9	8, 43	-29, 9	8, 43	-29, 9
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			21.2 (6.01)	-4.0 (4.46)	21.3 (6.28)	-5.0 (5.81)	21.3 (6.14)	-4.6 (5.22)	21.3 (6.14)	-4.6 (5.22)
	Median			21.0	-3.0	21.0	-4.0	21.0	-3.0	21.0	-3.0
	Min, Max			8, 43	-20, 5	7, 38	-36, 8	7, 43	-36, 8	7, 43	-36, 8
On-treatment Week 7	n			142	142	156	156	298	298	298	298

Negative subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			20.7 (6.15)	-4.8 (4.78)	20.8 (6.22)	-5.7 (6.02)	20.7 (6.17)	-5.3 (5.48)	20.7 (6.17)	-5.3 (5.48)
	Median			20.0	-4.0	21.0	-4.0	20.0	-4.0	20.0	-4.0
	Min, Max			8, 43	-22, 4	7, 39	-36, 7	7, 43	-36, 7	7, 43	-36, 7
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	19.7 (6.04)	-3.5 (4.89)	20.6 (6.07)	-4.9 (4.88)	20.3 (6.19)	-6.2 (6.23)	20.5 (6.13)	-5.6 (5.66)	20.2 (6.10)	-5.0 (5.53)
	Median	20.0	-2.0	20.0	-4.0	20.0	-5.0	20.0	-5.0	20.0	-4.0
	Min, Max	8, 38	-19, 6	8, 41	-21, 4	7, 34	-36, 7	7, 41	-36, 7	7, 41	-36, 7
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			20.1 (6.25)	-5.6 (5.15)	19.5 (6.03)	-7.0 (6.49)	19.8 (6.14)	-6.3 (5.92)	19.8 (6.14)	-6.3 (5.92)
	Median			19.0	-5.0	19.0	-6.0	19.0	-5.5	19.0	-5.5
	Min, Max			7, 42	-22, 7	7, 33	-36, 7	7, 42	-36, 7	7, 42	-36, 7
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	19.2 (6.06)	-3.9 (5.06)							19.2 (6.06)	-3.9 (5.06)
	Median	20.0	-2.5							20.0	-2.5
	Min, Max	8, 37	-22, 5							8, 37	-22, 5
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			19.4 (6.44)	-6.1 (5.56)	19.3 (5.76)	-7.1 (6.17)	19.3 (6.08)	-6.6 (5.90)	19.3 (6.08)	-6.6 (5.90)
	Median			19.0	-6.0	19.0	-6.0	19.0	-6.0	19.0	-6.0

Negative subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			7, 43	-24, 10	7, 31	-36, 5	7, 43	-36, 10	7, 43	-36, 10
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	18.7 (5.90)	-4.3 (5.15)							18.7 (5.90)	-4.3 (5.15)
	Median	19.0	-3.0							19.0	-3.0
	Min, Max	7, 36	-19, 13							7, 36	-19, 13
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			18.6 (6.19)	-7.1 (5.34)	18.8 (5.81)	-7.5 (6.44)	18.7 (5.98)	-7.3 (5.95)	18.7 (5.98)	-7.3 (5.95)
	Median			18.0	-7.0	18.5	-6.5	18.0	-7.0	18.0	-7.0
	Min, Max			7, 38	-26, 7	7, 31	-36, 5	7, 38	-36, 7	7, 38	-36, 7
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	18.4 (5.88)	-4.7 (5.78)							18.4 (5.88)	-4.7 (5.78)
	Median	19.0	-4.0							19.0	-4.0
	Min, Max	8, 34	-24, 13							8, 34	-24, 13
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			18.1 (5.86)	-7.3 (5.19)	18.4 (5.82)	-7.9 (6.50)	18.3 (5.83)	-7.6 (5.92)	18.3 (5.83)	-7.6 (5.92)
	Median			17.0	-7.0	18.0	-7.0	18.0	-7.0	18.0	-7.0
	Min, Max			7, 38	-27, 5	7, 33	-36, 6	7, 38	-36, 6	7, 38	-36, 6

Negative subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	17.9 (5.98)	-5.1 (5.68)							17.9 (5.98)	-5.1 (5.68)
	Median	18.0	-4.0							18.0	-4.0
	Min, Max	7, 34	-24, 12							7, 34	-24, 12
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			17.5 (6.20)	-8.1 (5.79)	18.2 (6.12)	-8.2 (6.84)	17.9 (6.16)	-8.2 (6.37)	17.9 (6.16)	-8.2 (6.37)
	Median			17.0	-9.0	18.0	-7.0	17.0	-8.0	17.0	-8.0
	Min, Max			7, 38	-25, 4	7, 35	-36, 6	7, 38	-36, 6	7, 38	-36, 6
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	17.7 (5.84)	-5.7 (5.56)							17.7 (5.84)	-5.7 (5.56)
	Median	18.0	-4.0							18.0	-4.0
	Min, Max	7, 36	-25, 3							7, 36	-25, 3
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			16.8 (5.99)	-8.5 (5.59)	17.8 (6.07)	-8.6 (6.88)	17.4 (6.04)	-8.5 (6.32)	17.4 (6.04)	-8.5 (6.32)
	Median			16.0	-9.0	17.0	-8.0	17.0	-8.0	17.0	-8.0
	Min, Max			7, 38	-25, 4	7, 33	-36, 7	7, 38	-36, 7	7, 38	-36, 7
On-treatment Week 34	n			91	91	114	114	205	205	205	205

Negative subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			17.0 (6.34)	-8.4 (5.82)	17.1 (5.99)	-9.3 (6.39)	17.1 (6.14)	-8.9 (6.14)	17.1 (6.14)	-8.9 (6.14)
	Median			16.0	-9.0	16.5	-9.0	16.0	-9.0	16.0	-9.0
	Min, Max			7, 38	-27, 4	7, 32	-36, 5	7, 38	-36, 5	7, 38	-36, 5
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	20.3 (6.33)	-4.3 (6.53)							20.3 (6.33)	-4.3 (6.53)
	Median	21.0	-2.0							21.0	-2.0
	Min, Max	9, 31	-25, 2							9, 31	-25, 2
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			21.7 (7.86)	-6.4 (5.92)	20.9 (6.42)	-7.0 (7.38)	21.2 (6.99)	-6.8 (6.73)	21.2 (6.99)	-6.8 (6.73)
	Median			20.0	-6.0	22.0	-5.0	20.0	-6.0	20.0	-6.0
	Min, Max			8, 38	-19, 4	7, 33	-36, 2	7, 38	-36, 4	7, 38	-36, 4
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	19.8 (7.13)	-4.8 (7.15)							19.8 (7.13)	-4.8 (7.15)
	Median	20.0	-3.0							20.0	-3.0
	Min, Max	8, 33	-26, 1							8, 33	-26, 1
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			21.4 (8.06)	-6.7 (5.87)	20.9 (5.92)	-6.8 (7.57)	21.1 (6.87)	-6.8 (6.79)	21.1 (6.87)	-6.8 (6.79)
	Median			21.0	-6.0	21.0	-5.0	21.0	-5.0	21.0	-5.0

Negative subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			8, 38	-18, 4	7, 31	-36, 3	7, 38	-36, 4	7, 38	-36, 4
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	19.0 (8.26)	-5.3 (8.14)							19.0 (8.26)	-5.3 (8.14)
	Median	21.0	-5.0							21.0	-5.0
	Min, Max	8, 33	-26, 3							8, 33	-26, 3
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			20.4 (8.40)	-7.4 (6.40)	20.8 (7.10)	-7.0 (8.01)	20.6 (7.59)	-7.2 (7.27)	20.6 (7.59)	-7.2 (7.27)
	Median			21.0	-7.0	19.5	-5.0	21.0	-6.0	21.0	-6.0
	Min, Max			7, 38	-18, 4	7, 35	-36, 3	7, 38	-36, 4	7, 38	-36, 4
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	18.9 (6.75)	-4.2 (6.00)	20.3 (7.19)	-5.1 (6.41)	19.4 (6.97)	-6.8 (7.00)	19.9 (7.09)	-6.0 (6.75)	19.6 (7.01)	-5.5 (6.61)
	Median	19.0	-4.0	20.0	-4.0	19.0	-7.0	19.0	-6.0	19.0	-5.0
	Min, Max	7, 39	-26, 12	7, 43	-27, 10	7, 42	-36, 7	7, 43	-36, 10	7, 43	-36, 12

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	41.2 (10.31)		49.9 (8.90)		49.5 (8.28)		49.7 (8.59)		47.6 (9.77)	
	Median	41.0		48.0		48.5		48.0		47.0	
	Min, Max	20, 69		34, 83		36, 84		34, 84		20, 84	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	39.6 (10.49)	-1.5 (4.06)	47.0 (9.76)	-2.9 (5.66)	46.0 (9.39)	-3.6 (6.89)	46.5 (9.58)	-3.2 (6.30)	44.8 (10.25)	-2.8 (5.87)
	Median	39.0	-1.0	46.0	-2.0	46.0	-2.0	46.0	-2.0	44.0	-2.0
	Min, Max	20, 70	-18, 12	18, 81	-21, 18	18, 83	-44, 21	18, 83	-44, 21	18, 83	-44, 21
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	38.3 (9.89)	-2.9 (5.30)	44.0 (10.37)	-5.7 (7.42)	43.2 (9.80)	-6.4 (8.35)	43.6 (10.08)	-6.1 (7.90)	42.2 (10.29)	-5.2 (7.43)
	Median	38.0	-2.0	42.0	-5.0	43.0	-4.0	43.0	-4.0	42.0	-4.0
	Min, Max	18, 65	-20, 13	16, 85	-28, 22	16, 79	-62, 8	16, 85	-62, 22	16, 85	-62, 22
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	37.3 (10.00)	-3.9 (6.06)	41.2 (9.63)	-8.3 (7.97)	40.2 (10.18)	-9.3 (9.65)	40.7 (9.91)	-8.8 (8.87)	39.8 (10.04)	-7.5 (8.49)
	Median	37.0	-3.0	40.0	-7.0	41.0	-7.0	40.0	-7.0	40.0	-6.0
	Min, Max	18, 63	-26, 14	16, 73	-36, 9	18, 69	-64, 10	16, 73	-64, 10	16, 73	-64, 14
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			39.9 (9.79)	-9.2 (9.16)	39.1 (10.46)	-10.3 (10.04)	39.5 (10.13)	-9.8 (9.63)	39.5 (10.13)	-9.8 (9.63)

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median			39.0	-7.0	40.0	-8.0	39.5	-8.0	39.5	-8.0
	Min, Max			16, 75	-44, 8	18, 68	-64, 8	16, 75	-64, 8	16, 75	-64, 8
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			38.0 (10.25)	-11.2 (9.38)	38.3 (10.55)	-11.2 (10.11)	38.2 (10.39)	-11.2 (9.75)	38.2 (10.39)	-11.2 (9.75)
	Median			37.0	-10.0	39.0	-9.0	38.0	-10.0	38.0	-10.0
	Min, Max			16, 79	-46, 7	16, 64	-64, 10	16, 79	-64, 10	16, 79	-64, 10
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	35.9 (11.12)	-5.3 (9.27)	37.3 (10.51)	-11.9 (9.62)	37.2 (10.12)	-12.2 (10.55)	37.3 (10.29)	-12.0 (10.11)	36.9 (10.54)	-10.1 (10.33)
	Median	35.0	-5.0	36.0	-12.0	39.0	-10.0	37.0	-11.0	36.0	-9.0
	Min, Max	16, 69	-29, 35	17, 84	-46, 7	16, 62	-64, 9	16, 84	-64, 9	16, 84	-64, 35
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			36.6 (10.38)	-12.5 (10.11)	36.2 (10.15)	-13.3 (10.56)	36.4 (10.25)	-13.0 (10.33)	36.4 (10.25)	-13.0 (10.33)
	Median			36.0	-11.5	35.5	-12.0	36.0	-12.0	36.0	-12.0
	Min, Max			16, 88	-50, 11	16, 58	-64, 12	16, 88	-64, 12	16, 88	-64, 12
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	34.2 (10.55)	-6.7 (8.77)							34.2 (10.55)	-6.7 (8.77)
	Median	33.0	-5.0							33.0	-5.0

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	16, 65	-31, 20							16, 65	-31, 20
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			35.4 (10.32)	-13.6 (10.92)	35.2 (10.32)	-14.0 (10.47)	35.3 (10.30)	-13.8 (10.67)	35.3 (10.30)	-13.8 (10.67)
	Median			34.0	-13.0	34.0	-12.0	34.0	-12.0	34.0	-12.0
	Min, Max			16, 69	-57, 11	16, 58	-65, 4	16, 69	-65, 11	16, 69	-65, 11
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	32.8 (9.52)	-7.8 (8.38)							32.8 (9.52)	-7.8 (8.38)
	Median	33.0	-6.0							33.0	-6.0
	Min, Max	16, 58	-29, 12							16, 58	-29, 12
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			32.8 (8.93)	-15.8 (10.13)	33.8 (10.14)	-15.4 (10.78)	33.3 (9.59)	-15.6 (10.47)	33.3 (9.59)	-15.6 (10.47)
	Median			32.0	-15.0	32.5	-14.0	32.0	-15.0	32.0	-15.0
	Min, Max			16, 58	-53, 8	16, 58	-65, 8	16, 58	-65, 8	16, 58	-65, 8
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	32.5 (10.47)	-8.4 (9.97)							32.5 (10.47)	-8.4 (9.97)
	Median	31.0	-8.0							31.0	-8.0
	Min, Max	16, 62	-33, 21							16, 62	-33, 21

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			32.0 (9.06)	-16.5 (10.34)	33.1 (10.14)	-16.1 (10.65)	32.6 (9.65)	-16.3 (10.49)	32.6 (9.65)	-16.3 (10.49)
	Median			31.0	-16.0	32.0	-15.5	32.0	-16.0	32.0	-16.0
	Min, Max			16, 59	-50, 9	16, 56	-66, 4	16, 59	-66, 9	16, 59	-66, 9
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	31.6 (10.64)	-9.3 (9.62)							31.6 (10.64)	-9.3 (9.62)
	Median	31.0	-8.0							31.0	-8.0
	Min, Max	16, 63	-34, 11							16, 63	-34, 11
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			31.3 (9.75)	-17.7 (10.20)	32.4 (10.89)	-16.9 (11.05)	31.9 (10.37)	-17.3 (10.65)	31.9 (10.37)	-17.3 (10.65)
	Median			30.0	-17.0	32.0	-16.0	31.0	-17.0	31.0	-17.0
	Min, Max			16, 60	-54, 4	16, 58	-67, 9	16, 60	-67, 9	16, 60	-67, 9
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	30.8 (10.76)	-10.7 (9.79)							30.8 (10.76)	-10.7 (9.79)
	Median	30.0	-10.0							30.0	-10.0
	Min, Max	16, 62	-36, 11							16, 62	-36, 11

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			29.9 (9.09)	-18.5 (10.35)	31.9 (11.02)	-17.4 (11.47)	31.0 (10.22)	-17.9 (10.97)	31.0 (10.22)	-17.9 (10.97)
	Median			30.0	-17.5	31.0	-16.0	31.0	-17.0	31.0	-17.0
	Min, Max			16, 57	-57, 5	16, 64	-67, 19	16, 64	-67, 19	16, 64	-67, 19
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			29.6 (9.08)	-18.8 (10.42)	30.6 (10.70)	-18.7 (10.93)	30.1 (10.00)	-18.8 (10.68)	30.1 (10.00)	-18.8 (10.68)
	Median			29.0	-19.0	30.5	-18.0	30.0	-18.0	30.0	-18.0
	Min, Max			16, 56	-52, 5	16, 58	-67, 5	16, 58	-67, 5	16, 58	-67, 5
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	40.5 (11.60)	-6.2 (10.94)							40.5 (11.60)	-6.2 (10.94)
	Median	41.0	-3.0							41.0	-3.0
	Min, Max	20, 62	-33, 9							20, 62	-33, 9
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			38.0 (9.07)	-14.0 (12.62)	41.1 (10.23)	-13.3 (13.47)	39.8 (9.78)	-13.6 (12.98)	39.8 (9.78)	-13.6 (12.98)
	Median			38.0	-12.5	39.0	-10.0	39.0	-11.0	39.0	-11.0
	Min, Max			18, 55	-51, 3	17, 56	-67, 4	17, 56	-67, 4	17, 56	-67, 4
On-treatment Week 44	n	15	15							15	15

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	38.5 (10.32)	-7.5 (11.51)							38.5 (10.32)	-7.5 (11.51)
	Median	39.0	-4.0							39.0	-4.0
	Min, Max	20, 53	-37, 5							20, 53	-37, 5
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			38.8 (9.37)	-13.2 (12.91)	41.0 (10.99)	-13.2 (13.64)	40.0 (10.24)	-13.2 (13.17)	40.0 (10.24)	-13.2 (13.17)
	Median			38.5	-13.0	39.0	-11.0	39.0	-12.0	39.0	-12.0
	Min, Max			20, 61	-47, 9	17, 62	-67, 3	17, 62	-67, 9	17, 62	-67, 9
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	38.2 (11.00)	-7.7 (12.72)							38.2 (11.00)	-7.7 (12.72)
	Median	40.0	-3.0							40.0	-3.0
	Min, Max	20, 56	-37, 6							20, 56	-37, 6
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			35.8 (9.75)	-16.9 (14.74)	39.0 (10.52)	-15.3 (13.89)	37.6 (10.18)	-16.0 (14.10)	37.6 (10.18)	-16.0 (14.10)
	Median			35.0	-15.0	37.0	-15.0	37.0	-15.0	37.0	-15.0
	Min, Max			18, 53	-58, 7	17, 55	-67, 0	17, 55	-67, 7	17, 55	-67, 7
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	34.7 (12.94)	-6.4 (11.72)	39.2 (14.42)	-10.7 (13.12)	36.3 (13.16)	-13.3 (13.11)	37.8 (13.87)	-12.0 (13.16)	37.0 (13.70)	-10.6 (13.03)

General psychopathology subscale		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	32.0	-5.5	39.0	-10.5	35.0	-14.0	37.0	-12.0	35.0	-10.0
	Min, Max	16, 69	-37, 35	16, 88	-58, 22	16, 68	-67, 21	16, 88	-67, 22	16, 88	-67, 35

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline value are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-34　PANSS 5 因子モデル別合計スコア変化量
（20 試験：ロナセンテープ貼付期　Open 52 週）

DSP-5423P Dosed Population

Negative symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	19.1 (5.41)		21.2 (5.30)		21.9 (5.22)		21.5 (5.27)		20.9 (5.40)	
	Median	19.0		21.0		22.0		21.0		21.0	
	Min, Max	6, 33		11, 36		9, 41		9, 41		6, 41	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	18.0 (5.28)	-1.0 (2.29)	20.2 (5.47)	-1.0 (2.51)	20.5 (5.37)	-1.3 (3.33)	20.4 (5.42)	-1.2 (2.94)	19.8 (5.47)	-1.1 (2.79)
	Median	18.0	0.0	20.0	-0.5	20.0	0.0	20.0	0.0	20.0	0.0
	Min, Max	6, 32	-12, 5	8, 36	-10, 10	8, 40	-22, 9	8, 40	-22, 10	6, 40	-22, 10

Negative symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	17.6 (5.24)	-1.6 (3.05)	19.0 (5.26)	-2.0 (3.34)	19.2 (5.60)	-2.7 (4.51)	19.1 (5.42)	-2.3 (3.98)	18.7 (5.41)	-2.1 (3.77)
	Median	17.0	-1.0	18.0	-1.0	19.0	-2.0	19.0	-2.0	18.0	-1.0
	Min, Max	6, 33	-12, 8	8, 36	-13, 6	6, 39	-31, 9	6, 39	-31, 9	6, 39	-31, 9
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	16.7 (5.12)	-2.4 (3.30)	18.1 (5.31)	-3.0 (3.90)	18.4 (5.50)	-3.5 (4.92)	18.2 (5.40)	-3.3 (4.45)	17.8 (5.36)	-3.0 (4.19)
	Median	17.0	-2.0	18.0	-2.0	18.5	-3.0	18.0	-3.0	18.0	-2.0
	Min, Max	7, 32	-13, 8	7, 37	-15, 6	6, 37	-30, 10	6, 37	-30, 10	6, 37	-30, 10
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			17.4 (5.42)	-3.6 (4.21)	17.6 (5.71)	-4.3 (5.41)	17.5 (5.56)	-3.9 (4.87)	17.5 (5.56)	-3.9 (4.87)
	Median			17.0	-3.0	17.5	-3.0	17.0	-3.0	17.0	-3.0
	Min, Max			6, 36	-21, 6	6, 32	-35, 8	6, 36	-35, 8	6, 36	-35, 8
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			16.9 (5.42)	-4.2 (4.29)	17.0 (5.66)	-5.0 (5.70)	17.0 (5.54)	-4.6 (5.08)	17.0 (5.54)	-4.6 (5.08)
	Median			17.0	-3.0	17.0	-4.0	17.0	-4.0	17.0	-4.0
	Min, Max			6, 36	-21, 4	6, 32	-35, 8	6, 36	-35, 8	6, 36	-35, 8
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408

Negative symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	16.2 (5.47)	-3.1 (4.20)	17.0 (5.29)	-4.3 (4.45)	16.7 (5.66)	-5.4 (5.89)	16.8 (5.48)	-4.9 (5.28)	16.6 (5.48)	-4.4 (5.05)
	Median	17.0	-2.0	17.0	-4.0	17.0	-5.0	17.0	-4.0	17.0	-4.0
	Min, Max	6, 33	-14, 9	6, 35	-21, 4	6, 29	-35, 8	6, 35	-35, 8	6, 35	-35, 9
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			16.6 (5.33)	-4.8 (4.57)	15.8 (5.35)	-6.2 (6.02)	16.2 (5.34)	-5.5 (5.42)	16.2 (5.34)	-5.5 (5.42)
	Median			16.0	-4.0	15.5	-5.5	16.0	-5.0	16.0	-5.0
	Min, Max			6, 35	-21, 8	6, 26	-35, 8	6, 35	-35, 8	6, 35	-35, 8
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	15.6 (5.40)	-3.6 (4.21)							15.6 (5.40)	-3.6 (4.21)
	Median	16.0	-3.0							16.0	-3.0
	Min, Max	6, 31	-19, 4							6, 31	-19, 4
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			16.0 (5.50)	-5.3 (4.86)	15.8 (5.17)	-6.1 (5.80)	15.9 (5.32)	-5.7 (5.38)	15.9 (5.32)	-5.7 (5.38)
	Median			15.0	-5.0	16.0	-5.0	16.0	-5.0	16.0	-5.0
	Min, Max			6, 36	-21, 9	6, 29	-35, 6	6, 36	-35, 9	6, 36	-35, 9
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	15.1 (5.26)	-3.9 (4.38)							15.1 (5.26)	-3.9 (4.38)
	Median	15.0	-3.0							15.0	-3.0

Negative symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	6, 29	-15, 14							6, 29	-15, 14
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			15.5 (5.49)	-6.0 (4.79)	15.5 (5.25)	-6.5 (6.09)	15.5 (5.35)	-6.3 (5.52)	15.5 (5.35)	-6.3 (5.52)
	Median			15.0	-5.0	16.0	-5.0	16.0	-5.0	16.0	-5.0
	Min, Max			6, 33	-24, 7	6, 29	-35, 7	6, 33	-35, 7	6, 33	-35, 7
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	14.8 (5.28)	-4.2 (5.09)							14.8 (5.28)	-4.2 (5.09)
	Median	15.0	-4.0							15.0	-4.0
	Min, Max	6, 29	-20, 16							6, 29	-20, 16
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			15.0 (5.32)	-6.3 (4.78)	15.1 (5.13)	-6.7 (5.97)	15.1 (5.21)	-6.5 (5.44)	15.1 (5.21)	-6.5 (5.44)
	Median			14.0	-6.0	15.0	-6.0	15.0	-6.0	15.0	-6.0
	Min, Max			6, 33	-25, 7	6, 29	-35, 8	6, 33	-35, 8	6, 33	-35, 8
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	14.5 (5.40)	-4.6 (4.87)							14.5 (5.40)	-4.6 (4.87)
	Median	14.0	-4.0							14.0	-4.0
	Min, Max	6, 29	-20, 9							6, 29	-20, 9

Negative symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			14.4 (5.39)	-7.1 (4.85)	14.8 (5.42)	-7.1 (6.23)	14.6 (5.40)	-7.1 (5.63)	14.6 (5.40)	-7.1 (5.63)
	Median			14.0	-7.0	14.0	-7.0	14.0	-7.0	14.0	-7.0
	Min, Max			6, 33	-23, 3	6, 29	-35, 6	6, 33	-35, 6	6, 33	-35, 6
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	14.2 (5.17)	-5.3 (4.76)							14.2 (5.17)	-5.3 (4.76)
	Median	14.0	-5.0							14.0	-5.0
	Min, Max	6, 29	-20, 4							6, 29	-20, 4
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			14.0 (5.27)	-7.3 (4.70)	14.6 (5.51)	-7.3 (6.48)	14.3 (5.40)	-7.3 (5.74)	14.3 (5.40)	-7.3 (5.74)
	Median			13.0	-7.5	14.0	-7.0	14.0	-7.0	14.0	-7.0
	Min, Max			6, 33	-24, 3	6, 31	-35, 10	6, 33	-35, 10	6, 33	-35, 10
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			14.1 (5.64)	-7.2 (5.09)	14.0 (5.45)	-7.8 (6.12)	14.1 (5.52)	-7.5 (5.68)	14.1 (5.52)	-7.5 (5.68)
	Median			13.0	-7.0	13.5	-7.0	13.0	-7.0	13.0	-7.0
	Min, Max			6, 33	-26, 3	6, 29	-35, 6	6, 33	-35, 6	6, 33	-35, 6
On-treatment Week 36	n	17	17							17	17

Negative symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	17.2 (5.36)	-3.6 (5.37)							17.2 (5.36)	-3.6 (5.37)
	Median	18.0	-2.0							18.0	-2.0
	Min, Max	7, 26	-20, 1							7, 26	-20, 1
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			18.6 (6.67)	-5.7 (4.79)	17.7 (5.68)	-6.3 (7.04)	18.0 (6.06)	-6.1 (6.13)	18.0 (6.06)	-6.1 (6.13)
	Median			17.0	-4.5	18.0	-5.0	17.0	-5.0	17.0	-5.0
	Min, Max			8, 33	-16, 1	6, 29	-35, 1	6, 33	-35, 1	6, 33	-35, 1
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	16.9 (6.03)	-3.9 (6.08)							16.9 (6.03)	-3.9 (6.08)
	Median	18.0	-2.0							18.0	-2.0
	Min, Max	6, 26	-21, 2							6, 26	-21, 2
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			18.1 (7.01)	-6.2 (4.87)	17.5 (5.01)	-6.3 (7.17)	17.8 (5.92)	-6.2 (6.19)	17.8 (5.92)	-6.2 (6.19)
	Median			17.0	-5.5	18.0	-5.0	17.0	-5.0	17.0	-5.0
	Min, Max			7, 33	-16, 0	6, 25	-35, 2	6, 33	-35, 2	6, 33	-35, 2
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	16.4 (6.98)	-4.4 (7.11)							16.4 (6.98)	-4.4 (7.11)
	Median	18.0	-3.0							18.0	-3.0

Negative symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	6, 28	-21, 6							6, 28	-21, 6
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			17.2 (7.46)	-6.9 (5.55)	17.5 (5.85)	-6.5 (7.62)	17.3 (6.51)	-6.7 (6.72)	17.3 (6.51)	-6.7 (6.72)
	Median			15.0	-7.0	17.0	-5.5	17.0	-6.0	17.0	-6.0
	Min, Max			6, 33	-17, 0	6, 29	-35, 3	6, 33	-35, 3	6, 33	-35, 3
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	15.3 (6.07)	-3.8 (5.42)	16.8 (6.34)	-4.4 (5.79)	16.1 (6.35)	-5.7 (6.63)	16.4 (6.35)	-5.1 (6.25)	16.2 (6.29)	-4.7 (6.07)
	Median	15.0	-4.0	16.0	-3.0	16.0	-5.0	16.0	-4.0	16.0	-4.0
	Min, Max	6, 33	-21, 9	6, 36	-26, 10	6, 37	-35, 10	6, 37	-35, 10	6, 37	-35, 10

Excitement		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	9.2 (3.50)		11.8 (3.39)		11.2 (3.38)		11.5 (3.40)		10.9 (3.56)	
	Median	9.0		12.0		11.0		11.0		11.0	
	Min, Max	4, 21		4, 24		4, 21		4, 24		4, 24	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	8.7 (3.25)	-0.5 (2.27)	11.0 (3.96)	-0.8 (2.89)	10.2 (3.54)	-1.0 (2.45)	10.6 (3.77)	-0.9 (2.68)	10.1 (3.75)	-0.8 (2.59)

Excitement		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	8.0	0.0	11.0	-1.0	10.0	-1.0	10.0	-1.0	10.0	-1.0
	Min, Max	4, 17	-10, 8	4, 24	-11, 11	4, 21	-10, 12	4, 24	-11, 12	4, 24	-11, 12
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	8.4 (3.24)	-0.7 (2.73)	10.2 (3.97)	-1.5 (3.39)	9.3 (3.36)	-1.9 (2.78)	9.7 (3.69)	-1.7 (3.10)	9.4 (3.62)	-1.4 (3.03)
	Median	8.0	0.0	10.0	-1.0	9.0	-2.0	9.0	-1.0	9.0	-1.0
	Min, Max	4, 18	-10, 10	4, 27	-12, 13	4, 21	-12, 6	4, 27	-12, 13	4, 27	-12, 13
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	8.2 (3.19)	-0.9 (2.87)	9.4 (3.42)	-2.1 (3.03)	8.7 (3.08)	-2.4 (3.23)	9.0 (3.26)	-2.3 (3.13)	8.8 (3.26)	-1.9 (3.12)
	Median	8.0	-1.0	9.0	-2.0	8.0	-2.0	9.0	-2.0	9.0	-2.0
	Min, Max	4, 17	-10, 12	4, 21	-11, 9	4, 17	-12, 5	4, 21	-12, 9	4, 21	-12, 12
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			9.1 (3.28)	-2.4 (3.42)	8.4 (2.92)	-2.6 (3.44)	8.8 (3.11)	-2.5 (3.43)	8.8 (3.11)	-2.5 (3.43)
	Median			9.0	-2.0	8.0	-2.0	8.0	-2.0	8.0	-2.0
	Min, Max			4, 20	-12, 7	4, 18	-12, 7	4, 20	-12, 7	4, 20	-12, 7
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			8.7 (3.17)	-2.9 (3.41)	8.3 (3.37)	-2.8 (3.82)	8.5 (3.28)	-2.8 (3.63)	8.5 (3.28)	-2.8 (3.63)
	Median			9.0	-3.0	8.0	-2.0	8.0	-2.0	8.0	-2.0
	Min, Max			4, 18	-12, 7	4, 25	-13, 10	4, 25	-13, 10	4, 25	-13, 10

Excitement		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	7.8 (3.32)	-1.4 (3.49)	8.5 (3.53)	-3.1 (3.68)	8.0 (2.91)	-3.1 (3.76)	8.2 (3.23)	-3.1 (3.71)	8.1 (3.25)	-2.6 (3.73)
	Median	7.0	-2.0	8.0	-3.0	8.0	-2.0	8.0	-3.0	8.0	-2.0
	Min, Max	4, 20	-11, 8	4, 22	-12, 7	4, 18	-13, 8	4, 22	-13, 8	4, 22	-13, 8
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			8.4 (3.57)	-3.1 (4.10)	7.9 (2.94)	-3.2 (3.93)	8.1 (3.26)	-3.2 (4.01)	8.1 (3.26)	-3.2 (4.01)
	Median			8.0	-3.0	8.0	-3.0	8.0	-3.0	8.0	-3.0
	Min, Max			4, 24	-14, 10	4, 16	-16, 10	4, 24	-16, 10	4, 24	-16, 10
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	7.4 (2.97)	-1.7 (3.28)							7.4 (2.97)	-1.7 (3.28)
	Median	7.0	-2.0							7.0	-2.0
	Min, Max	4, 18	-10, 6							4, 18	-10, 6
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			7.9 (3.42)	-3.6 (4.13)	7.8 (3.17)	-3.4 (3.88)	7.8 (3.29)	-3.5 (3.99)	7.8 (3.29)	-3.5 (3.99)
	Median			8.0	-4.0	7.5	-3.0	8.0	-3.0	8.0	-3.0
	Min, Max			4, 22	-16, 11	4, 18	-13, 8	4, 22	-16, 11	4, 22	-16, 11

Excitement		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	7.1 (2.76)	-2.0 (3.41)							7.1 (2.76)	-2.0 (3.41)
	Median	7.0	-2.0							7.0	-2.0
	Min, Max	4, 19	-10, 6							4, 19	-10, 6
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			6.9 (2.47)	-4.5 (3.59)	7.3 (2.92)	-3.8 (3.82)	7.1 (2.72)	-4.1 (3.72)	7.1 (2.72)	-4.1 (3.72)
	Median			7.0	-4.0	7.0	-4.0	7.0	-4.0	7.0	-4.0
	Min, Max			4, 15	-15, 4	4, 15	-13, 6	4, 15	-15, 6	4, 15	-15, 6
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	7.1 (3.31)	-2.0 (3.66)							7.1 (3.31)	-2.0 (3.66)
	Median	6.0	-2.0							6.0	-2.0
	Min, Max	4, 20	-10, 14							4, 20	-10, 14
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			6.7 (2.58)	-4.6 (3.44)	7.3 (2.81)	-3.9 (3.78)	7.0 (2.71)	-4.2 (3.63)	7.0 (2.71)	-4.2 (3.63)
	Median			6.0	-4.0	7.0	-3.5	6.0	-4.0	6.0	-4.0
	Min, Max			4, 15	-11, 5	4, 14	-13, 7	4, 15	-13, 7	4, 15	-13, 7
On-treatment Week 24	n	89	89							89	89

Excitement		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	6.8 (2.90)	-2.5 (3.47)							6.8 (2.90)	-2.5 (3.47)
	Median	6.0	-2.0							6.0	-2.0
	Min, Max	4, 19	-11, 5							4, 19	-11, 5
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			6.7 (2.76)	-4.7 (3.52)	6.9 (3.01)	-4.4 (3.89)	6.8 (2.89)	-4.5 (3.72)	6.8 (2.89)	-4.5 (3.72)
	Median			6.0	-4.0	6.0	-4.0	6.0	-4.0	6.0	-4.0
	Min, Max			4, 15	-11, 4	4, 19	-13, 5	4, 19	-13, 5	4, 19	-13, 5
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	6.7 (3.07)	-2.6 (3.35)							6.7 (3.07)	-2.6 (3.35)
	Median	6.0	-2.0							6.0	-2.0
	Min, Max	4, 19	-10, 5							4, 19	-10, 5
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			6.4 (2.59)	-4.9 (3.52)	6.9 (3.04)	-4.3 (3.93)	6.7 (2.85)	-4.6 (3.76)	6.7 (2.85)	-4.6 (3.76)
	Median			5.0	-5.0	6.0	-4.0	6.0	-4.0	6.0	-4.0
	Min, Max			4, 17	-13, 5	4, 19	-13, 5	4, 19	-13, 5	4, 19	-13, 5
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			6.2 (2.40)	-5.1 (3.60)	6.6 (2.88)	-4.5 (3.81)	6.5 (2.68)	-4.8 (3.72)	6.5 (2.68)	-4.8 (3.72)
	Median			6.0	-5.0	6.0	-4.0	6.0	-4.0	6.0	-4.0

Excitement		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			4, 16	-13, 4	4, 19	-13, 5	4, 19	-13, 5	4, 19	-13, 5
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	9.5 (4.09)	-0.6 (3.52)							9.5 (4.09)	-0.6 (3.52)
	Median	9.0	-1.0							9.0	-1.0
	Min, Max	4, 22	-6, 8							4, 22	-6, 8
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			8.4 (3.03)	-3.0 (4.22)	8.8 (3.04)	-2.5 (2.93)	8.6 (3.01)	-2.7 (3.50)	8.6 (3.01)	-2.7 (3.50)
	Median			8.0	-2.0	9.0	-2.0	8.0	-2.0	8.0	-2.0
	Min, Max			4, 16	-14, 4	4, 15	-8, 2	4, 16	-14, 4	4, 16	-14, 4
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	8.7 (2.63)	-1.1 (2.87)							8.7 (2.63)	-1.1 (2.87)
	Median	9.0	-1.0							9.0	-1.0
	Min, Max	4, 13	-6, 4							4, 13	-6, 4
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			8.7 (3.45)	-2.6 (4.50)	9.2 (3.64)	-2.2 (3.55)	9.0 (3.52)	-2.4 (3.96)	9.0 (3.52)	-2.4 (3.96)
	Median			8.0	-2.0	10.0	-2.0	8.0	-2.0	8.0	-2.0
	Min, Max			4, 19	-13, 7	4, 19	-12, 5	4, 19	-13, 7	4, 19	-13, 7

Excitement		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	8.8 (2.76)	-1.3 (2.81)							8.8 (2.76)	-1.3 (2.81)
	Median	9.0	-1.0							9.0	-1.0
	Min, Max	4, 14	-6, 4							4, 14	-6, 4
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			8.3 (2.93)	-3.3 (4.47)	8.5 (2.96)	-2.7 (3.08)	8.4 (2.91)	-2.9 (3.71)	8.4 (2.91)	-2.9 (3.71)
	Median			8.0	-2.0	8.5	-1.5	8.0	-2.0	8.0	-2.0
	Min, Max			4, 15	-13, 6	4, 14	-11, 2	4, 15	-13, 6	4, 15	-13, 6
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	7.8 (4.05)	-1.3 (4.34)	9.6 (5.04)	-2.2 (5.01)	8.4 (4.11)	-2.8 (4.54)	9.0 (4.64)	-2.5 (4.78)	8.7 (4.52)	-2.2 (4.70)
	Median	7.0	-1.0	8.0	-2.0	8.0	-3.0	8.0	-2.0	8.0	-2.0
	Min, Max	4, 22	-11, 14	4, 27	-13, 13	4, 25	-16, 12	4, 27	-16, 13	4, 27	-16, 14

Cognitive disorders		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	14.7 (4.05)		16.9 (3.59)		16.8 (3.85)		16.9 (3.72)		16.3 (3.92)	
	Median	14.0		17.0		17.0		17.0		16.0	
	Min, Max	6, 29		8, 27		8, 30		8, 30		6, 30	

Cognitive disorders		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	14.1 (3.90)	-0.5 (1.70)	16.0 (3.68)	-0.9 (2.09)	15.7 (3.85)	-1.1 (2.52)	15.8 (3.76)	-1.0 (2.31)	15.4 (3.87)	-0.9 (2.18)
	Median	14.0	0.0	15.0	-1.0	15.0	-1.0	15.0	-1.0	15.0	0.0
	Min, Max	6, 26	-8, 4	8, 28	-7, 7	6, 26	-14, 10	6, 28	-14, 10	6, 28	-14, 10
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	13.5 (3.80)	-1.1 (2.15)	15.1 (3.79)	-1.8 (2.54)	14.8 (3.91)	-2.1 (3.27)	15.0 (3.85)	-2.0 (2.93)	14.6 (3.88)	-1.7 (2.77)
	Median	13.0	-1.0	15.0	-1.0	15.0	-1.0	15.0	-1.0	14.0	-1.0
	Min, Max	5, 24	-7, 6	8, 28	-10, 7	7, 26	-21, 9	7, 28	-21, 9	5, 28	-21, 9
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	13.2 (3.80)	-1.5 (2.97)	14.3 (3.69)	-2.5 (2.77)	13.8 (4.04)	-3.2 (3.38)	14.0 (3.88)	-2.9 (3.11)	13.8 (3.87)	-2.5 (3.13)
	Median	13.0	-1.0	14.0	-2.0	14.0	-3.0	14.0	-2.0	14.0	-2.0
	Min, Max	5, 24	-16, 5	6, 26	-12, 5	6, 24	-21, 4	6, 26	-21, 5	5, 26	-21, 5
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			13.9 (3.85)	-2.8 (2.98)	13.5 (4.14)	-3.5 (3.78)	13.7 (4.00)	-3.1 (3.43)	13.7 (4.00)	-3.1 (3.43)
	Median			14.0	-2.0	13.0	-3.0	13.0	-2.0	13.0	-2.0
	Min, Max			6, 26	-15, 4	5, 25	-24, 3	5, 26	-24, 4	5, 26	-24, 4

Cognitive disorders		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			13.3 (3.86)	-3.4 (3.38)	13.2 (4.12)	-3.7 (3.92)	13.3 (3.99)	-3.6 (3.67)	13.3 (3.99)	-3.6 (3.67)
	Median			13.0	-3.0	13.0	-3.0	13.0	-3.0	13.0	-3.0
	Min, Max			6, 26	-16, 4	5, 24	-24, 4	5, 26	-24, 4	5, 26	-24, 4
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	12.6 (3.86)	-2.1 (3.94)	12.9 (3.82)	-3.8 (3.41)	12.9 (4.06)	-4.0 (3.99)	12.9 (3.94)	-3.9 (3.73)	12.8 (3.92)	-3.4 (3.88)
	Median	12.0	-2.0	12.0	-4.0	13.0	-3.0	13.0	-4.0	13.0	-3.0
	Min, Max	5, 25	-19, 6	6, 27	-16, 5	5, 24	-24, 4	5, 27	-24, 5	5, 27	-24, 6
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			12.6 (4.01)	-4.2 (3.73)	12.5 (4.08)	-4.4 (4.22)	12.6 (4.04)	-4.3 (3.99)	12.6 (4.04)	-4.3 (3.99)
	Median			12.0	-4.0	13.0	-4.0	12.0	-4.0	12.0	-4.0
	Min, Max			5, 27	-17, 6	5, 22	-25, 4	5, 27	-25, 6	5, 27	-25, 6
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	12.1 (3.74)	-2.6 (4.18)							12.1 (3.74)	-2.6 (4.18)
	Median	12.0	-2.0							12.0	-2.0
	Min, Max	5, 25	-17, 6							5, 25	-17, 6
On-treatment Week 14	n			127	127	142	142	269	269	269	269

Cognitive disorders		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			12.2 (4.02)	-4.5 (3.93)	12.2 (3.94)	-4.7 (4.08)	12.2 (3.97)	-4.6 (4.00)	12.2 (3.97)	-4.6 (4.00)
	Median			12.0	-4.0	12.0	-4.0	12.0	-4.0	12.0	-4.0
	Min, Max			5, 26	-17, 6	5, 24	-25, 3	5, 26	-25, 6	5, 26	-25, 6
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	11.5 (3.38)	-3.2 (4.04)							11.5 (3.38)	-3.2 (4.04)
	Median	11.0	-2.0							11.0	-2.0
	Min, Max	5, 21	-17, 5							5, 21	-17, 5
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			11.5 (3.71)	-5.3 (3.55)	11.6 (3.72)	-5.2 (4.26)	11.5 (3.71)	-5.2 (3.94)	11.5 (3.71)	-5.2 (3.94)
	Median			11.0	-5.0	11.0	-5.0	11.0	-5.0	11.0	-5.0
	Min, Max			5, 23	-19, 3	5, 22	-25, 2	5, 23	-25, 3	5, 23	-25, 3
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	11.4 (3.61)	-3.4 (4.37)							11.4 (3.61)	-3.4 (4.37)
	Median	11.0	-2.0							11.0	-2.0
	Min, Max	5, 20	-17, 6							5, 20	-17, 6
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			11.1 (3.48)	-5.5 (3.49)	11.3 (3.85)	-5.4 (4.29)	11.2 (3.68)	-5.5 (3.93)	11.2 (3.68)	-5.5 (3.93)
	Median			10.0	-6.0	11.0	-5.0	11.0	-5.0	11.0	-5.0

Cognitive disorders		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			5, 23	-18, 3	5, 23	-24, 1	5, 23	-24, 3	5, 23	-24, 3
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	11.2 (3.75)	-3.6 (4.30)							11.2 (3.75)	-3.6 (4.30)
	Median	11.0	-3.0							11.0	-3.0
	Min, Max	5, 22	-18, 5							5, 22	-18, 5
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			10.8 (3.74)	-5.9 (3.68)	11.3 (4.00)	-5.5 (4.43)	11.1 (3.88)	-5.7 (4.10)	11.1 (3.88)	-5.7 (4.10)
	Median			10.0	-6.0	11.0	-5.0	10.0	-6.0	10.0	-6.0
	Min, Max			5, 23	-17, 2	5, 23	-24, 5	5, 23	-24, 5	5, 23	-24, 5
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	11.0 (3.83)	-3.9 (4.45)							11.0 (3.83)	-3.9 (4.45)
	Median	10.0	-3.0							10.0	-3.0
	Min, Max	5, 22	-19, 5							5, 22	-19, 5
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			10.3 (3.65)	-6.2 (3.75)	11.1 (3.94)	-5.8 (4.48)	10.7 (3.82)	-6.0 (4.16)	10.7 (3.82)	-6.0 (4.16)
	Median			10.0	-6.0	11.0	-5.0	10.0	-6.0	10.0	-6.0
	Min, Max			5, 23	-19, 2	5, 23	-25, 1	5, 23	-25, 2	5, 23	-25, 2

Cognitive disorders		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			10.4 (3.64)	-6.2 (3.78)	10.7 (3.85)	-6.1 (4.33)	10.6 (3.75)	-6.1 (4.09)	10.6 (3.75)	-6.1 (4.09)
	Median			10.0	-6.0	10.5	-6.0	10.0	-6.0	10.0	-6.0
	Min, Max			5, 23	-18, 1	5, 24	-25, 1	5, 24	-25, 1	5, 24	-25, 1
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	13.0 (4.11)	-2.4 (4.21)							13.0 (4.11)	-2.4 (4.21)
	Median	13.0	-1.0							13.0	-1.0
	Min, Max	6, 21	-14, 2							6, 21	-14, 2
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			12.7 (4.57)	-4.3 (3.46)	13.3 (4.11)	-4.6 (5.02)	13.0 (4.27)	-4.5 (4.39)	13.0 (4.27)	-4.5 (4.39)
	Median			12.5	-4.0	13.0	-4.0	13.0	-4.0	13.0	-4.0
	Min, Max			5, 23	-14, 0	5, 24	-24, 1	5, 24	-24, 1	5, 24	-24, 1
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	11.8 (3.47)	-3.3 (4.22)							11.8 (3.47)	-3.3 (4.22)
	Median	12.0	-2.0							12.0	-2.0
	Min, Max	6, 17	-14, 1							6, 17	-14, 1
On-treatment Week 50	n			20	20	25	25	45	45	45	45

Cognitive disorders		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			12.7 (4.52)	-4.2 (3.75)	13.7 (4.62)	-4.2 (5.03)	13.3 (4.55)	-4.2 (4.46)	13.3 (4.55)	-4.2 (4.46)
	Median			12.0	-3.0	14.0	-3.0	13.0	-3.0	13.0	-3.0
	Min, Max			5, 23	-16, 0	5, 24	-24, 1	5, 24	-24, 1	5, 24	-24, 1
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	11.5 (3.62)	-3.4 (4.59)							11.5 (3.62)	-3.4 (4.59)
	Median	12.0	-1.0							12.0	-1.0
	Min, Max	6, 17	-14, 2							6, 17	-14, 2
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			11.9 (4.27)	-4.8 (3.77)	13.3 (4.75)	-4.7 (5.21)	12.7 (4.54)	-4.7 (4.58)	12.7 (4.54)	-4.7 (4.58)
	Median			12.0	-4.0	12.5	-4.0	12.0	-4.0	12.0	-4.0
	Min, Max			5, 20	-15, 0	5, 24	-24, 0	5, 24	-24, 0	5, 24	-24, 0
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	12.1 (4.26)	-2.5 (4.45)	13.3 (4.94)	-3.6 (4.40)	12.4 (4.52)	-4.4 (4.67)	12.9 (4.75)	-4.0 (4.55)	12.7 (4.64)	-3.6 (4.57)
	Median	12.0	-1.5	13.0	-3.0	12.0	-4.0	12.0	-4.0	12.0	-3.0
	Min, Max	5, 25	-19, 6	5, 28	-18, 7	5, 25	-25, 10	5, 28	-25, 10	5, 28	-25, 10

Positive symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change

Positive symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	12.5 (4.16)		16.1 (3.09)		15.8 (3.23)		16.0 (3.16)		15.1 (3.76)	
	Median	12.0		16.0		16.0		16.0		15.0	
	Min, Max	4, 25		9, 26		7, 27		7, 27		4, 27	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	11.9 (4.17)	-0.6 (1.73)	14.9 (3.49)	-1.2 (2.22)	14.3 (3.48)	-1.5 (2.32)	14.6 (3.49)	-1.3 (2.27)	13.9 (3.86)	-1.2 (2.17)
	Median	12.0	0.0	15.0	-1.0	14.0	-1.0	14.0	-1.0	14.0	-1.0
	Min, Max	4, 23	-7, 6	6, 24	-9, 7	5, 27	-11, 7	5, 27	-11, 7	4, 27	-11, 7
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	11.3 (4.05)	-1.1 (2.39)	13.9 (3.70)	-2.2 (2.83)	13.2 (3.60)	-2.6 (2.86)	13.5 (3.66)	-2.4 (2.85)	13.0 (3.88)	-2.1 (2.79)
	Median	11.0	-1.0	13.0	-2.0	13.0	-2.0	13.0	-2.0	13.0	-2.0
	Min, Max	4, 21	-11, 4	4, 24	-12, 7	4, 27	-13, 3	4, 27	-13, 7	4, 27	-13, 7
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	10.8 (4.03)	-1.6 (3.24)	12.7 (3.91)	-3.3 (3.25)	11.9 (3.89)	-3.9 (3.53)	12.3 (3.92)	-3.6 (3.40)	11.9 (4.00)	-3.1 (3.47)
	Median	10.0	-2.0	13.0	-3.0	12.0	-3.0	12.0	-3.0	12.0	-2.5
	Min, Max	4, 23	-12, 11	4, 25	-13, 7	4, 26	-14, 3	4, 26	-14, 7	4, 26	-14, 11
On-treatment Week 6	n			156	156	166	166	322	322	322	322

Positive symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			12.2 (3.76)	-3.7 (3.49)	11.3 (4.02)	-4.4 (3.94)	11.8 (3.91)	-4.1 (3.75)	11.8 (3.91)	-4.1 (3.75)
	Median			12.0	-3.0	11.0	-4.0	12.0	-4.0	12.0	-4.0
	Min, Max			4, 23	-13, 3	4, 26	-15, 3	4, 26	-15, 3	4, 26	-15, 3
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			11.3 (3.64)	-4.6 (3.44)	11.2 (4.31)	-4.6 (4.31)	11.3 (4.00)	-4.6 (3.91)	11.3 (4.00)	-4.6 (3.91)
	Median			11.0	-4.0	11.0	-4.0	11.0	-4.0	11.0	-4.0
	Min, Max			4, 23	-15, 4	4, 26	-16, 4	4, 26	-16, 4	4, 26	-16, 4
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	10.0 (4.20)	-2.4 (3.99)	11.0 (3.87)	-4.9 (3.75)	10.9 (4.05)	-4.9 (4.17)	10.9 (3.96)	-4.9 (3.97)	10.7 (4.05)	-4.2 (4.13)
	Median	9.0	-2.0	11.0	-5.0	11.0	-4.0	11.0	-5.0	10.0	-4.0
	Min, Max	4, 23	-14, 16	4, 23	-15, 6	4, 26	-15, 3	4, 26	-15, 6	4, 26	-15, 16
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			10.5 (3.75)	-5.4 (3.76)	10.5 (4.14)	-5.2 (4.31)	10.5 (3.95)	-5.3 (4.05)	10.5 (3.95)	-5.3 (4.05)
	Median			10.0	-5.0	10.0	-5.0	10.0	-5.0	10.0	-5.0
	Min, Max			4, 23	-17, 2	4, 28	-17, 3	4, 28	-17, 3	4, 28	-17, 3
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	9.4 (3.69)	-2.8 (3.78)							9.4 (3.69)	-2.8 (3.78)
	Median	9.0	-2.0							9.0	-2.0

Positive symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	4, 21	-14, 6							4, 21	-14, 6
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			10.1 (4.13)	-5.7 (4.28)	10.0 (4.12)	-5.7 (4.32)	10.1 (4.12)	-5.7 (4.30)	10.1 (4.12)	-5.7 (4.30)
	Median			10.0	-6.0	10.0	-5.0	10.0	-6.0	10.0	-6.0
	Min, Max			4, 27	-17, 11	4, 28	-19, 4	4, 28	-19, 11	4, 28	-19, 11
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	8.9 (3.77)	-3.2 (4.07)							8.9 (3.77)	-3.2 (4.07)
	Median	9.0	-3.0							9.0	-3.0
	Min, Max	4, 22	-14, 6							4, 22	-14, 6
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			8.9 (3.23)	-6.9 (3.97)	9.0 (3.21)	-6.5 (4.25)	9.0 (3.21)	-6.7 (4.12)	9.0 (3.21)	-6.7 (4.12)
	Median			8.0	-7.0	9.0	-6.0	9.0	-6.0	9.0	-6.0
	Min, Max			4, 16	-18, 2	4, 19	-19, 2	4, 19	-19, 2	4, 19	-19, 2
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	8.7 (3.92)	-3.5 (4.30)							8.7 (3.92)	-3.5 (4.30)
	Median	8.5	-3.0							8.5	-3.0
	Min, Max	4, 22	-14, 9							4, 22	-14, 9

Positive symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			8.7 (3.46)	-7.0 (4.23)	8.8 (3.39)	-6.8 (4.29)	8.8 (3.42)	-6.9 (4.25)	8.8 (3.42)	-6.9 (4.25)
	Median			8.0	-7.0	9.0	-6.5	9.0	-7.0	9.0	-7.0
	Min, Max			4, 17	-18, 2	4, 19	-20, 2	4, 19	-20, 2	4, 19	-20, 2
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	8.3 (3.79)	-4.0 (4.16)							8.3 (3.79)	-4.0 (4.16)
	Median	8.0	-4.0							8.0	-4.0
	Min, Max	4, 22	-14, 8							4, 22	-14, 8
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			8.2 (3.44)	-7.6 (4.22)	8.5 (3.47)	-7.0 (4.43)	8.4 (3.45)	-7.3 (4.34)	8.4 (3.45)	-7.3 (4.34)
	Median			8.0	-7.0	8.0	-7.0	8.0	-7.0	8.0	-7.0
	Min, Max			4, 17	-18, 2	4, 20	-20, 3	4, 20	-20, 3	4, 20	-20, 3
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	8.1 (3.88)	-4.3 (4.46)							8.1 (3.88)	-4.3 (4.46)
	Median	8.0	-4.0							8.0	-4.0
	Min, Max	4, 22	-16, 6							4, 22	-16, 6
On-treatment Week 30	n			92	92	113	113	205	205	205	205

Positive symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			7.9 (3.31)	-7.9 (4.33)	8.1 (3.42)	-7.4 (4.48)	8.0 (3.36)	-7.6 (4.40)	8.0 (3.36)	-7.6 (4.40)
	Median			7.5	-8.0	8.0	-7.0	8.0	-7.0	8.0	-7.0
	Min, Max			4, 16	-18, 3	4, 20	-19, 3	4, 20	-19, 3	4, 20	-19, 3
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			7.7 (3.32)	-8.0 (4.44)	7.8 (3.32)	-7.8 (4.34)	7.8 (3.31)	-7.9 (4.37)	7.8 (3.31)	-7.9 (4.37)
	Median			7.0	-8.0	8.0	-7.0	8.0	-8.0	8.0	-8.0
	Min, Max			4, 17	-18, 4	4, 20	-19, 3	4, 20	-19, 4	4, 20	-19, 4
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	10.5 (5.56)	-1.9 (4.33)							10.5 (5.56)	-1.9 (4.33)
	Median	10.0	-2.0							10.0	-2.0
	Min, Max	4, 28	-9, 8							4, 28	-9, 8
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			9.5 (3.58)	-5.8 (5.36)	10.3 (3.36)	-3.9 (3.31)	10.0 (3.44)	-4.7 (4.35)	10.0 (3.44)	-4.7 (4.35)
	Median			9.0	-5.0	9.0	-4.0	9.0	-4.0	9.0	-4.0
	Min, Max			4, 16	-16, 3	4, 19	-11, 1	4, 19	-16, 3	4, 19	-16, 3
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	8.9 (2.64)	-2.9 (3.36)							8.9 (2.64)	-2.9 (3.36)
	Median	9.0	-2.0							9.0	-2.0

Positive symptoms		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	4, 12	-10, 2							4, 12	-10, 2
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			9.8 (3.52)	-5.5 (5.45)	10.3 (3.79)	-3.9 (3.64)	10.1 (3.64)	-4.6 (4.54)	10.1 (3.64)	-4.6 (4.54)
	Median			10.0	-5.0	10.0	-4.0	10.0	-4.0	10.0	-4.0
	Min, Max			4, 17	-16, 4	4, 19	-11, 4	4, 19	-16, 4	4, 19	-16, 4
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	9.0 (3.00)	-2.9 (3.86)							9.0 (3.00)	-2.9 (3.86)
	Median	10.0	-2.0							10.0	-2.0
	Min, Max	4, 13	-10, 3							4, 13	-10, 3
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			9.1 (3.44)	-6.6 (5.29)	9.7 (3.20)	-4.3 (3.06)	9.4 (3.28)	-5.3 (4.28)	9.4 (3.28)	-5.3 (4.28)
	Median			9.0	-6.0	9.5	-4.0	9.0	-5.0	9.0	-5.0
	Min, Max			4, 16	-17, 1	4, 19	-11, 1	4, 19	-17, 1	4, 19	-17, 1
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	9.8 (5.04)	-2.6 (5.13)	11.4 (5.36)	-4.7 (5.35)	10.1 (5.05)	-5.6 (5.00)	10.8 (5.25)	-5.2 (5.20)	10.5 (5.21)	-4.5 (5.29)
	Median	9.0	-2.0	11.0	-4.0	9.0	-5.0	10.0	-5.0	10.0	-4.0
	Min, Max	4, 28	-16, 16	4, 27	-18, 11	4, 28	-19, 4	4, 28	-19, 11	4, 28	-19, 16

Anxiety/depression		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	11.3 (3.82)		14.6 (3.90)		14.2 (3.68)		14.4 (3.79)		13.6 (4.03)	
	Median	11.0		15.0		14.0		14.0		14.0	
	Min, Max	5, 26		5, 27		7, 26		5, 27		5, 27	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	11.2 (3.94)	-0.1 (1.65)	13.7 (3.94)	-0.9 (2.10)	13.2 (3.76)	-1.0 (2.02)	13.4 (3.85)	-1.0 (2.06)	12.9 (3.99)	-0.7 (1.99)
	Median	11.0	0.0	13.5	0.0	13.0	0.0	13.0	0.0	13.0	0.0
	Min, Max	5, 26	-5, 6	5, 26	-8, 6	5, 27	-10, 5	5, 27	-10, 6	5, 27	-10, 6
On-treatment Week 2	n	129	129	179	179	183	183	362	362	491	491
	Mean (SD)	10.5 (3.55)	-0.8 (2.22)	12.7 (4.19)	-1.9 (2.67)	12.3 (3.88)	-1.9 (2.74)	12.5 (4.04)	-1.9 (2.70)	12.0 (4.01)	-1.6 (2.63)
	Median	10.0	0.0	12.0	-1.0	12.0	-1.0	12.0	-1.0	12.0	-1.0
	Min, Max	5, 19	-12, 6	5, 29	-10, 7	5, 24	-14, 3	5, 29	-14, 7	5, 29	-14, 7
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	10.5 (3.60)	-0.8 (2.20)	11.9 (3.92)	-2.7 (3.05)	11.4 (3.74)	-2.6 (3.40)	11.7 (3.83)	-2.7 (3.23)	11.3 (3.80)	-2.2 (3.10)
	Median	10.0	-1.0	11.0	-2.0	11.0	-2.0	11.0	-2.0	11.0	-2.0
	Min, Max	5, 22	-6, 5	5, 24	-13, 4	5, 20	-17, 5	5, 24	-17, 5	5, 24	-17, 5
On-treatment Week 6	n			156	156	166	166	322	322	322	322

Anxiety/depression		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			11.3 (3.97)	-3.0 (3.29)	11.1 (3.77)	-2.9 (3.31)	11.2 (3.86)	-3.0 (3.29)	11.2 (3.86)	-3.0 (3.29)
	Median			11.0	-3.0	11.0	-3.0	11.0	-3.0	11.0	-3.0
	Min, Max			5, 24	-12, 6	5, 23	-13, 5	5, 24	-13, 6	5, 24	-13, 6
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			10.7 (3.77)	-3.7 (3.29)	10.9 (3.65)	-3.1 (3.37)	10.8 (3.70)	-3.4 (3.35)	10.8 (3.70)	-3.4 (3.35)
	Median			11.0	-3.5	11.0	-3.0	11.0	-3.0	11.0	-3.0
	Min, Max			5, 24	-12, 5	5, 20	-12, 4	5, 24	-12, 5	5, 24	-12, 5
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	10.1 (4.06)	-1.2 (3.26)	10.5 (3.79)	-3.9 (3.38)	10.5 (3.46)	-3.4 (3.37)	10.5 (3.61)	-3.6 (3.38)	10.4 (3.75)	-2.9 (3.52)
	Median	10.0	-1.0	10.0	-4.0	10.0	-3.0	10.0	-3.0	10.0	-2.5
	Min, Max	5, 25	-9, 14	5, 25	-13, 3	5, 18	-12, 5	5, 25	-13, 5	5, 25	-13, 14
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			10.2 (3.79)	-4.1 (3.48)	10.2 (3.44)	-3.8 (3.28)	10.2 (3.60)	-4.0 (3.37)	10.2 (3.60)	-4.0 (3.37)
	Median			10.0	-4.0	10.0	-3.0	10.0	-4.0	10.0	-4.0
	Min, Max			5, 27	-15, 3	5, 18	-13, 4	5, 27	-15, 4	5, 27	-15, 4
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	9.6 (3.61)	-1.6 (2.82)							9.6 (3.61)	-1.6 (2.82)
	Median	9.0	-1.5							9.0	-1.5

Anxiety/depression		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	5, 21	-11, 6							5, 21	-11, 6
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			9.9 (3.80)	-4.4 (3.78)	9.7 (3.42)	-4.2 (3.36)	9.8 (3.60)	-4.3 (3.56)	9.8 (3.60)	-4.3 (3.56)
	Median			10.0	-4.0	9.0	-4.0	9.0	-4.0	9.0	-4.0
	Min, Max			5, 22	-17, 3	5, 19	-13, 4	5, 22	-17, 4	5, 22	-17, 4
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	9.4 (3.56)	-1.7 (3.01)							9.4 (3.56)	-1.7 (3.01)
	Median	9.0	-1.0							9.0	-1.0
	Min, Max	5, 21	-10, 7							5, 21	-10, 7
On-treatment Week 18	n			109	109	126	126	235	235	235	235
	Mean (SD)			9.1 (3.21)	-4.8 (3.58)	9.6 (3.58)	-4.3 (3.62)	9.4 (3.41)	-4.5 (3.60)	9.4 (3.41)	-4.5 (3.60)
	Median			9.0	-4.0	9.0	-4.0	9.0	-4.0	9.0	-4.0
	Min, Max			5, 20	-16, 3	5, 19	-13, 4	5, 20	-16, 4	5, 20	-16, 4
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	9.1 (3.45)	-2.1 (2.99)							9.1 (3.45)	-2.1 (2.99)
	Median	9.0	-2.0							9.0	-2.0
	Min, Max	5, 17	-11, 8							5, 17	-11, 8

Anxiety/depression		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			9.1 (3.41)	-4.9 (3.75)	9.5 (3.58)	-4.4 (3.59)	9.3 (3.50)	-4.6 (3.67)	9.3 (3.50)	-4.6 (3.67)
	Median			8.0	-5.0	9.0	-4.0	9.0	-5.0	9.0	-5.0
	Min, Max			5, 19	-15, 6	5, 18	-13, 3	5, 19	-15, 6	5, 19	-15, 6
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	9.0 (3.54)	-2.1 (2.81)							9.0 (3.54)	-2.1 (2.81)
	Median	9.0	-2.0							9.0	-2.0
	Min, Max	5, 18	-11, 4							5, 18	-11, 4
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			8.9 (3.55)	-5.1 (3.67)	9.3 (3.66)	-4.6 (3.79)	9.1 (3.61)	-4.8 (3.74)	9.1 (3.61)	-4.8 (3.74)
	Median			8.0	-5.0	9.0	-5.0	8.0	-5.0	8.0	-5.0
	Min, Max			5, 21	-19, 2	5, 20	-13, 7	5, 21	-19, 7	5, 21	-19, 7
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	8.6 (3.63)	-2.7 (2.74)							8.6 (3.63)	-2.7 (2.74)
	Median	8.0	-2.0							8.0	-2.0
	Min, Max	5, 18	-13, 2							5, 18	-13, 2
On-treatment Week 30	n			92	92	113	113	205	205	205	205

Anxiety/depression		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			8.6 (3.31)	-5.3 (3.79)	9.0 (3.79)	-4.8 (3.99)	8.8 (3.58)	-5.1 (3.90)	8.8 (3.58)	-5.1 (3.90)
	Median			8.0	-6.0	8.0	-5.0	8.0	-5.0	8.0	-5.0
	Min, Max			5, 21	-19, 5	5, 23	-13, 10	5, 23	-19, 10	5, 23	-19, 10
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			8.4 (3.04)	-5.5 (3.68)	8.6 (3.46)	-5.2 (3.72)	8.5 (3.28)	-5.3 (3.69)	8.5 (3.28)	-5.3 (3.69)
	Median			7.0	-6.0	8.0	-5.0	8.0	-5.0	8.0	-5.0
	Min, Max			5, 18	-15, 5	5, 18	-15, 3	5, 18	-15, 5	5, 18	-15, 5
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	12.2 (3.11)	-1.5 (3.54)							12.2 (3.11)	-1.5 (3.54)
	Median	12.0	0.0							12.0	0.0
	Min, Max	6, 18	-10, 2							6, 18	-10, 2
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			11.6 (3.33)	-4.0 (5.20)	11.7 (3.68)	-4.1 (3.73)	11.7 (3.50)	-4.0 (4.36)	11.7 (3.50)	-4.0 (4.36)
	Median			11.5	-3.5	11.0	-4.0	11.0	-4.0	11.0	-4.0
	Min, Max			6, 19	-17, 3	5, 19	-11, 3	5, 19	-17, 3	5, 19	-17, 3
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	11.6 (3.11)	-1.9 (3.91)							11.6 (3.11)	-1.9 (3.91)
	Median	12.0	-1.0							12.0	-1.0

Anxiety/depression		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	6, 18	-11, 2							6, 18	-11, 2
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			11.5 (3.10)	-4.1 (5.40)	11.6 (3.73)	-4.0 (3.53)	11.6 (3.43)	-4.0 (4.41)	11.6 (3.43)	-4.0 (4.41)
	Median			11.0	-3.5	11.0	-4.0	11.0	-4.0	11.0	-4.0
	Min, Max			6, 19	-16, 6	5, 20	-11, 2	5, 20	-16, 6	5, 20	-16, 6
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	11.7 (3.77)	-2.2 (4.19)							11.7 (3.77)	-2.2 (4.19)
	Median	12.0	-1.0							12.0	-1.0
	Min, Max	6, 20	-11, 2							6, 20	-11, 2
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			10.4 (3.12)	-5.5 (5.95)	10.7 (3.55)	-5.1 (3.61)	10.6 (3.33)	-5.3 (4.71)	10.6 (3.33)	-5.3 (4.71)
	Median			10.0	-5.0	10.0	-5.5	10.0	-5.0	10.0	-5.0
	Min, Max			6, 15	-20, 4	5, 17	-11, 0	5, 17	-20, 4	5, 17	-20, 4
On-treatment (LOCF)	n	130	130	196	196	192	192	388	388	518	518
	Mean (SD)	9.8 (4.42)	-1.5 (3.47)	11.2 (4.92)	-3.4 (4.24)	10.3 (4.45)	-3.9 (4.20)	10.8 (4.71)	-3.6 (4.22)	10.5 (4.65)	-3.1 (4.15)
	Median	9.0	-1.0	11.0	-3.0	10.0	-4.0	10.0	-4.0	10.0	-2.5
	Min, Max	5, 25	-13, 14	5, 27	-20, 7	5, 23	-15, 10	5, 27	-20, 10	5, 27	-20, 14

Anxiety/depression		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline value are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-35　CGI-S スコア変化量

(20 試験：ロナセンテープ貼付期　Open 52 週)

DSP-5423P Dosed Population

		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	131		196		194		390		521	
	Mean (SD)	4.02 (1.049)		4.84 (0.780)		4.92 (0.734)		4.88 (0.758)		4.66 (0.918)	
	Median	4.00		5.00		5.00		5.00		5.00	
	Min, Max	2, 7		3, 7		3, 7		3, 7		2, 7	
On-treatment Week 1	n	129	129	196	196	192	192	388	388	517	517
	Mean (SD)	3.87 (1.041)	-0.15 (0.452)	4.63 (0.871)	-0.21 (0.557)	4.57 (0.815)	-0.35 (0.693)	4.60 (0.843)	-0.28 (0.631)	4.42 (0.950)	-0.25 (0.594)
	Median	4.00	0.00	5.00	0.00	4.50	0.00	5.00	0.00	4.00	0.00
	Min, Max	1, 7	-2, 1	2, 7	-2, 2	3, 7	-3, 2	2, 7	-3, 2	1, 7	-3, 2
On-treatment Week 2	n	129	129	179	179	184	184	363	363	492	492
	Mean (SD)	3.73 (1.073)	-0.29 (0.687)	4.28 (0.938)	-0.51 (0.803)	4.29 (0.922)	-0.64 (0.901)	4.29 (0.929)	-0.57 (0.855)	4.14 (0.998)	-0.50 (0.824)
	Median	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
		Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	1, 6	-3, 1	2, 7	-2, 3	2, 7	-5, 1	2, 7	-5, 3	1, 7	-5, 3
On-treatment Week 4	n	125	125	167	167	174	174	341	341	466	466
	Mean (SD)	3.59 (1.025)	-0.42 (0.935)	4.00 (0.957)	-0.79 (0.856)	3.97 (1.028)	-0.95 (1.047)	3.99 (0.993)	-0.87 (0.960)	3.88 (1.015)	-0.75 (0.974)
	Median	4.00	0.00	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	1, 6	-4, 3	1, 6	-3, 1	1, 6	-6, 1	1, 6	-6, 1	1, 6	-6, 3
On-treatment Week 6	n			156	156	166	166	322	322	322	322
	Mean (SD)			3.87 (1.029)	-0.89 (1.013)	3.81 (1.050)	-1.11 (1.079)	3.84 (1.039)	-1.00 (1.052)	3.84 (1.039)	-1.00 (1.052)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			1, 6	-4, 2	1, 6	-6, 1	1, 6	-6, 2	1, 6	-6, 2
On-treatment Week 7	n			142	142	156	156	298	298	298	298
	Mean (SD)			3.68 (1.028)	-1.08 (1.048)	3.79 (1.060)	-1.15 (1.085)	3.73 (1.045)	-1.12 (1.066)	3.73 (1.045)	-1.12 (1.066)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			1, 6	-4, 2	1, 7	-6, 1	1, 7	-6, 2	1, 7	-6, 2
On-treatment Week 8	n	117	117	137	137	154	154	291	291	408	408
	Mean (SD)	3.38 (1.151)	-0.62 (1.112)	3.53 (1.036)	-1.22 (1.083)	3.65 (1.070)	-1.29 (1.126)	3.59 (1.054)	-1.26 (1.104)	3.53 (1.085)	-1.08 (1.142)
	Median	3.00	-1.00	3.00	-1.00	4.00	-1.00	4.00	-1.00	3.00	-1.00
	Min, Max	1, 6	-4, 4	1, 7	-4, 1	1, 6	-6, 1	1, 7	-6, 1	1, 7	-6, 4

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
		Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 10	n			134	134	146	146	280	280	280	280
	Mean (SD)			3.44 (0.993)	-1.29 (1.096)	3.50 (1.046)	-1.44 (1.151)	3.47 (1.019)	-1.37 (1.125)	3.47 (1.019)	-1.37 (1.125)
	Median			3.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			1, 7	-4, 2	1, 6	-6, 1	1, 7	-6, 2	1, 7	-6, 2
On-treatment Week 12	n	104	104							104	104
	Mean (SD)	3.14 (0.999)	-0.79 (1.021)							3.14 (0.999)	-0.79 (1.021)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	1, 6	-4, 1							1, 6	-4, 1
On-treatment Week 14	n			127	127	142	142	269	269	269	269
	Mean (SD)			3.35 (1.094)	-1.38 (1.168)	3.41 (1.053)	-1.51 (1.213)	3.38 (1.071)	-1.45 (1.192)	3.38 (1.071)	-1.45 (1.192)
	Median			3.00	-1.00	3.00	-1.50	3.00	-1.00	3.00	-1.00
	Min, Max			1, 7	-4, 3	1, 7	-6, 1	1, 7	-6, 3	1, 7	-6, 3
On-treatment Week 16	n	99	99							99	99
	Mean (SD)	3.16 (0.987)	-0.78 (1.074)							3.16 (0.987)	-0.78 (1.074)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	1, 6	-4, 2							1, 6	-4, 2
On-treatment Week 18	n			109	109	126	126	235	235	235	235

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	PLCB-to-FLEX DOSE (N = 131) Change	40MG-to-FLEX DOSE (N = 196) Observed	40MG-to-FLEX DOSE (N = 196) Change	80MG-to-FLEX DOSE (N = 194) Observed	80MG-to-FLEX DOSE (N = 194) Change	Active-to-FLEX DOSE (N = 390) Observed	Active-to-FLEX DOSE (N = 390) Change	Overall-to-FLEX DOSE (N = 521) Observed	Overall-to-FLEX DOSE (N = 521) Change
	Mean (SD)			3.01 (0.887)	-1.71 (1.057)	3.23 (0.956)	-1.67 (1.165)	3.13 (0.930)	-1.69 (1.114)	3.13 (0.930)	-1.69 (1.114)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 1	1, 5	-6, 0	1, 5	-6, 1	1, 5	-6, 1
On-treatment Week 20	n	90	90							90	90
	Mean (SD)	3.06 (1.021)	-0.86 (1.127)							3.06 (1.021)	-0.86 (1.127)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	1, 6	-4, 3							1, 6	-4, 3
On-treatment Week 22	n			107	107	122	122	229	229	229	229
	Mean (SD)			2.95 (0.965)	-1.75 (1.125)	3.12 (0.950)	-1.76 (1.157)	3.04 (0.959)	-1.76 (1.140)	3.04 (0.959)	-1.76 (1.140)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 1	1, 5	-6, 0	1, 5	-6, 1	1, 5	-6, 1
On-treatment Week 24	n	89	89							89	89
	Mean (SD)	2.99 (1.082)	-0.94 (1.190)							2.99 (1.082)	-0.94 (1.190)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	1, 6	-4, 3							1, 6	-4, 3
On-treatment Week 26	n			99	99	117	117	216	216	216	216
	Mean (SD)			2.85 (0.993)	-1.89 (1.142)	3.04 (0.986)	-1.85 (1.176)	2.95 (0.992)	-1.87 (1.158)	2.95 (0.992)	-1.87 (1.158)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
		Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			1, 5	-4, 1	1, 6	-6, 1	1, 6	-6, 1	1, 6	-6, 1
On-treatment Week 28	n	83	83							83	83
	Mean (SD)	2.95 (1.023)	-1.00 (1.115)							2.95 (1.023)	-1.00 (1.115)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	1, 6	-4, 2							1, 6	-4, 2
On-treatment Week 30	n			92	92	113	113	205	205	205	205
	Mean (SD)			2.75 (0.921)	-1.95 (1.083)	2.96 (0.944)	-1.93 (1.193)	2.87 (0.938)	-1.94 (1.142)	2.87 (0.938)	-1.94 (1.142)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 1	1, 6	-6, 1	1, 6	-6, 1	1, 6	-6, 1
On-treatment Week 34	n			91	91	114	114	205	205	205	205
	Mean (SD)			2.71 (0.886)	-1.98 (1.064)	2.87 (0.927)	-2.03 (1.193)	2.80 (0.910)	-2.00 (1.135)	2.80 (0.910)	-2.00 (1.135)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 1	1, 5	-6, 0	1, 5	-6, 1	1, 5	-6, 1
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	3.35 (1.320)	-0.47 (1.007)							3.35 (1.320)	-0.47 (1.007)
	Median	3.00	0.00							3.00	0.00
	Min, Max	1, 6	-3, 1							1, 6	-3, 1

Visit	Statistics	PLCB-to-FLEX DOSE (N = 131) Observed	Change	40MG-to-FLEX DOSE (N = 196) Observed	Change	80MG-to-FLEX DOSE (N = 194) Observed	Change	Active-to-FLEX DOSE (N = 390) Observed	Change	Overall-to-FLEX DOSE (N = 521) Observed	Change
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			3.30 (0.979)	-1.55 (1.317)	3.33 (1.000)	-1.41 (1.575)	3.32 (0.980)	-1.47 (1.457)	3.32 (0.980)	-1.47 (1.457)
	Median			4.00	-1.50	3.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-4, 0	1, 6	-6, 2	1, 6	-6, 2	1, 6	-6, 2
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	3.13 (1.125)	-0.53 (1.246)							3.13 (1.125)	-0.53 (1.246)
	Median	3.00	0.00							3.00	0.00
	Min, Max	1, 5	-3, 2							1, 5	-3, 2
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			3.45 (0.945)	-1.40 (1.314)	3.32 (0.945)	-1.36 (1.497)	3.38 (0.936)	-1.38 (1.403)	3.38 (0.936)	-1.38 (1.403)
	Median			4.00	-1.50	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			2, 5	-4, 1	1, 5	-6, 1	1, 5	-6, 1	1, 5	-6, 1
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	3.08 (1.188)	-0.62 (1.121)							3.08 (1.188)	-0.62 (1.121)
	Median	3.00	0.00							3.00	0.00
	Min, Max	1, 5	-3, 1							1, 5	-3, 1
On-treatment Week 58	n			17	17	22	22	39	39	39	39

		PLCB-to-FLEX DOSE (N = 131)		40MG-to-FLEX DOSE (N = 196)		80MG-to-FLEX DOSE (N = 194)		Active-to-FLEX DOSE (N = 390)		Overall-to-FLEX DOSE (N = 521)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			3.18 (0.883)	-1.65 (1.320)	3.14 (0.834)	-1.55 (1.471)	3.15 (0.844)	-1.59 (1.390)	3.15 (0.844)	-1.59 (1.390)
	Median			3.00	-2.00	3.00	-1.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-4, 0	1, 4	-6, 0	1, 4	-6, 0	1, 4	-6, 0
On-treatment (LOCF)	n	130	130	196	196	193	193	389	389	519	519
	Mean (SD)	3.39 (1.267)	-0.62 (1.290)	3.79 (1.466)	-1.05 (1.406)	3.53 (1.350)	-1.39 (1.410)	3.66 (1.413)	-1.22 (1.416)	3.59 (1.382)	-1.07 (1.408)
	Median	3.00	-1.00	4.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max	1, 6	-4, 4	1, 7	-4, 3	1, 7	-6, 2	1, 7	-6, 3	1, 7	-6, 4

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline value are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-36　PANSS 合計スコア変化量

(20 試験：ロナセンテープ貼付期　Open 52 週、性別)

DSP-5423P Dosed Population

Sex: Male		PLCB-to-FLEX DOSE (N = 85)		40MG-to-FLEX DOSE (N = 116)		80MG-to-FLEX DOSE (N = 115)		Active-to-FLEX DOSE (N = 231)		Overall-to-FLEX DOSE (N = 316)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	85		116		115		231		316	
	Mean (SD)	83.3 (19.17)		101.3 (14.35)		101.4 (14.18)		101.4 (14.24)		96.5 (17.62)	
	Median	84.0		99.0		99.0		99.0		97.0	
	Min, Max	38, 126		80, 142		80, 155		80, 155		38, 155	

Sex: Male		PLCB-to-FLEX DOSE (N = 85)		40MG-to-FLEX DOSE (N = 116)		80MG-to-FLEX DOSE (N = 115)		Active-to-FLEX DOSE (N = 231)		Overall-to-FLEX DOSE (N = 316)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 1	n	83	83	116	116	114	114	230	230	313	313
	Mean (SD)	80.7 (20.26)	-2.0 (6.22)	93.7 (17.70)	-7.7 (10.93)	94.5 (16.79)	-7.0 (12.04)	94.1 (17.22)	-7.3 (11.48)	90.5 (18.98)	-5.9 (10.60)
	Median	84.0	-2.0	91.5	-6.0	93.5	-6.0	92.0	-6.0	90.0	-4.0
	Min, Max	37, 133	-24, 14	45, 139	-41, 36	56, 154	-56, 36	45, 154	-56, 36	37, 154	-56, 36
On-treatment Week 2	n	83	83	108	108	109	109	217	217	300	300
	Mean (SD)	78.0 (19.88)	-5.1 (10.68)	87.3 (18.32)	-13.2 (14.81)	87.3 (16.92)	-14.3 (15.20)	87.3 (17.59)	-13.7 (14.99)	84.7 (18.69)	-11.3 (14.44)
	Median	75.0	-4.0	87.0	-12.0	88.0	-12.0	88.0	-12.0	85.0	-9.0
	Min, Max	38, 141	-35, 21	36, 131	-50, 37	50, 132	-70, 13	36, 132	-70, 37	36, 141	-70, 37
On-treatment Week 4	n	79	79	104	104	102	102	206	206	285	285
	Mean (SD)	74.5 (18.73)	-8.5 (10.38)	82.9 (19.01)	-17.7 (15.77)	81.5 (18.03)	-20.2 (17.49)	82.2 (18.50)	-18.9 (16.65)	80.1 (18.85)	-16.0 (15.86)
	Median	77.0	-8.0	82.5	-16.0	82.0	-17.5	82.0	-17.0	80.0	-14.0
	Min, Max	38, 128	-37, 23	34, 132	-63, 21	46, 138	-72, 17	34, 138	-72, 21	34, 138	-72, 23
On-treatment Week 6	n			99	99	96	96	195	195	195	195
	Mean (SD)			80.0 (18.79)	-20.3 (17.48)	78.8 (20.24)	-22.4 (19.67)	79.4 (19.47)	-21.3 (18.57)	79.4 (19.47)	-21.3 (18.57)
	Median			81.0	-18.0	80.5	-19.5	81.0	-19.0	81.0	-19.0
	Min, Max			34, 118	-73, 10	36, 136	-80, 12	34, 136	-80, 12	34, 136	-80, 12
On-treatment Week 7	n			92	92	89	89	181	181	181	181

Sex: Male		PLCB-to-FLEX DOSE (N = 85)		40MG-to-FLEX DOSE (N = 116)		80MG-to-FLEX DOSE (N = 115)		Active-to-FLEX DOSE (N = 231)		Overall-to-FLEX DOSE (N = 316)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			76.4 (19.35)	-24.4 (17.30)	75.7 (20.16)	-25.7 (21.35)	76.0 (19.70)	-25.1 (19.36)	76.0 (19.70)	-25.1 (19.36)
	Median			75.0	-25.0	78.0	-22.0	76.0	-24.0	76.0	-24.0
	Min, Max			32, 123	-76, 7	32, 139	-84, 24	32, 139	-84, 24	32, 139	-84, 24
On-treatment Week 8	n	76	76	90	90	89	89	179	179	255	255
	Mean (SD)	71.1 (19.62)	-12.2 (14.89)	74.6 (19.75)	-26.3 (18.28)	73.4 (19.74)	-28.0 (21.34)	74.0 (19.70)	-27.1 (19.82)	73.1 (19.68)	-22.7 (19.69)
	Median	70.5	-11.0	71.5	-26.5	74.0	-24.0	73.0	-25.0	72.0	-21.0
	Min, Max	35, 126	-51, 32	34, 123	-76, 9	30, 130	-86, 15	30, 130	-86, 15	30, 130	-86, 32
On-treatment Week 10	n			90	90	85	85	175	175	175	175
	Mean (SD)			72.7 (19.76)	-28.1 (18.71)	70.2 (19.46)	-30.9 (21.77)	71.5 (19.60)	-29.5 (20.24)	71.5 (19.60)	-29.5 (20.24)
	Median			69.0	-27.0	71.0	-29.0	71.0	-28.0	71.0	-28.0
	Min, Max			32, 123	-80, 12	30, 122	-92, 15	30, 123	-92, 15	30, 123	-92, 15
On-treatment Week 12	n	71	71							71	71
	Mean (SD)	68.8 (19.22)	-14.0 (16.81)							68.8 (19.22)	-14.0 (16.81)
	Median	67.0	-10.0							67.0	-10.0
	Min, Max	32, 137	-60, 33							32, 137	-60, 33
On-treatment Week 14	n			84	84	81	81	165	165	165	165
	Mean (SD)			70.3 (22.93)	-30.5 (21.50)	68.8 (18.37)	-31.5 (19.84)	69.6 (20.77)	-31.0 (20.65)	69.6 (20.77)	-31.0 (20.65)
	Median			67.5	-31.0	68.0	-28.0	68.0	-30.0	68.0	-30.0

Sex: Male		PLCB-to-FLEX DOSE (N = 85)		40MG-to-FLEX DOSE (N = 116)		80MG-to-FLEX DOSE (N = 115)		Active-to-FLEX DOSE (N = 231)		Overall-to-FLEX DOSE (N = 316)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			30, 158	-82, 32	30, 110	-87, 5	30, 158	-87, 32	30, 158	-87, 32
On-treatment Week 16	n	68	68							68	68
	Mean (SD)	65.1 (16.62)	-16.9 (17.14)							65.1 (16.62)	-16.9 (17.14)
	Median	63.0	-13.5							63.0	-13.5
	Min, Max	31, 116	-64, 23							31, 116	-64, 23
On-treatment Week 18	n			73	73	73	73	146	146	146	146
	Mean (SD)			64.8 (18.30)	-34.8 (19.12)	66.6 (17.63)	-33.5 (20.50)	65.7 (17.93)	-34.1 (19.76)	65.7 (17.93)	-34.1 (19.76)
	Median			64.0	-36.0	67.0	-32.0	66.0	-33.0	66.0	-33.0
	Min, Max			30, 106	-83, 7	30, 106	-86, 0	30, 106	-86, 7	30, 106	-86, 7
On-treatment Week 20	n	60	60							60	60
	Mean (SD)	65.1 (19.03)	-16.9 (20.64)							65.1 (19.03)	-16.9 (20.64)
	Median	63.0	-15.5							63.0	-15.5
	Min, Max	33, 116	-71, 47							33, 116	-71, 47
On-treatment Week 22	n			72	72	72	72	144	144	144	144
	Mean (SD)			63.2 (18.00)	-36.0 (19.64)	64.9 (18.31)	-35.3 (21.06)	64.1 (18.11)	-35.6 (20.30)	64.1 (18.11)	-35.6 (20.30)
	Median			65.0	-37.5	65.0	-33.5	65.0	-35.0	65.0	-35.0
	Min, Max			30, 102	-84, 14	33, 106	-88, 0	30, 106	-88, 14	30, 106	-88, 14

Sex: Male		PLCB-to-FLEX DOSE (N = 85)		40MG-to-FLEX DOSE (N = 116)		80MG-to-FLEX DOSE (N = 115)		Active-to-FLEX DOSE (N = 231)		Overall-to-FLEX DOSE (N = 316)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 24	n	60	60							60	60
	Mean (SD)	63.5 (18.44)	-18.9 (18.59)							63.5 (18.44)	-18.9 (18.59)
	Median	65.0	-14.5							65.0	-14.5
	Min, Max	32, 116	-58, 32							32, 116	-58, 32
On-treatment Week 26	n			67	67	67	67	134	134	134	134
	Mean (SD)			61.5 (18.60)	-39.0 (18.47)	62.7 (18.62)	-37.8 (21.12)	62.1 (18.55)	-38.4 (19.77)	62.1 (18.55)	-38.4 (19.77)
	Median			59.0	-41.0	64.0	-36.0	61.0	-38.0	61.0	-38.0
	Min, Max			30, 107	-83, 6	32, 108	-88, 0	30, 108	-88, 6	30, 108	-88, 6
On-treatment Week 28	n	57	57							57	57
	Mean (SD)	61.4 (18.38)	-21.8 (18.13)							61.4 (18.38)	-21.8 (18.13)
	Median	61.0	-21.0							61.0	-21.0
	Min, Max	34, 116	-62, 20							34, 116	-62, 20
On-treatment Week 30	n			62	62	66	66	128	128	128	128
	Mean (SD)			58.9 (17.71)	-40.0 (18.40)	61.6 (18.44)	-39.1 (20.95)	60.3 (18.07)	-39.6 (19.69)	60.3 (18.07)	-39.6 (19.69)
	Median			59.5	-41.5	63.5	-36.0	61.0	-38.0	61.0	-38.0
	Min, Max			30, 108	-83, 6	30, 110	-88, 0	30, 110	-88, 6	30, 110	-88, 6
On-treatment Week 34	n			61	61	66	66	127	127	127	127

Sex: Male		PLCB-to-FLEX DOSE (N = 85)		40MG-to-FLEX DOSE (N = 116)		80MG-to-FLEX DOSE (N = 115)		Active-to-FLEX DOSE (N = 231)		Overall-to-FLEX DOSE (N = 316)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			58.0 (17.85)	-40.9 (19.35)	59.6 (18.24)	-41.1 (20.07)	58.8 (18.00)	-41.0 (19.65)	58.8 (18.00)	-41.0 (19.65)
	Median			58.0	-42.0	60.0	-38.0	59.0	-40.0	59.0	-40.0
	Min, Max			30, 112	-89, 10	30, 107	-90, 0	30, 112	-90, 10	30, 112	-90, 10
On-treatment Week 36	n	11	11							11	11
	Mean (SD)	83.3 (22.60)	-7.5 (15.71)							83.3 (22.60)	-7.5 (15.71)
	Median	86.0	-11.0							86.0	-11.0
	Min, Max	56, 133	-32, 23							56, 133	-32, 23
On-treatment Week 42	n			10	10	15	15	25	25	25	25
	Mean (SD)			75.1 (17.89)	-27.8 (22.03)	75.6 (16.67)	-25.3 (15.67)	75.4 (16.80)	-26.3 (18.08)	75.4 (16.80)	-26.3 (18.08)
	Median			68.0	-30.5	75.0	-29.0	72.0	-29.0	72.0	-29.0
	Min, Max			58, 112	-58, 10	48, 107	-48, 0	48, 112	-58, 10	48, 112	-58, 10
On-treatment Week 44	n	10	10							10	10
	Mean (SD)	78.5 (17.17)	-10.4 (13.30)							78.5 (17.17)	-10.4 (13.30)
	Median	81.0	-10.5							81.0	-10.5
	Min, Max	54, 100	-35, 8							54, 100	-35, 8
On-treatment Week 50	n			10	10	15	15	25	25	25	25
	Mean (SD)			76.6 (21.31)	-26.3 (26.17)	75.0 (16.83)	-25.9 (16.21)	75.6 (18.34)	-26.0 (20.26)	75.6 (18.34)	-26.0 (20.26)
	Median			70.5	-29.5	74.0	-28.0	73.0	-28.0	73.0	-28.0

Sex: Male		PLCB-to-FLEX DOSE (N = 85)		40MG-to-FLEX DOSE (N = 116)		80MG-to-FLEX DOSE (N = 115)		Active-to-FLEX DOSE (N = 231)		Overall-to-FLEX DOSE (N = 316)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			53, 120	-58, 18	51, 107	-58, 0	51, 120	-58, 18	51, 120	-58, 18
On-treatment Week 52	n	8	8							8	8
	Mean (SD)	79.5 (19.96)	-9.5 (17.82)							79.5 (19.96)	-9.5 (17.82)
	Median	84.5	-5.0							84.5	-5.0
	Min, Max	51, 103	-37, 11							51, 103	-37, 11
On-treatment Week 58	n			9	9	15	15	24	24	24	24
	Mean (SD)			70.3 (19.35)	-32.7 (25.22)	75.0 (15.68)	-25.9 (15.55)	73.3 (16.88)	-28.4 (19.48)	73.3 (16.88)	-28.4 (19.48)
	Median			68.0	-31.0	74.0	-29.0	73.5	-30.0	73.5	-30.0
	Min, Max			42, 95	-66, 9	57, 107	-53, 0	42, 107	-66, 9	42, 107	-66, 9
On-treatment (LOCF)	n	84	84	116	116	114	114	230	230	314	314
	Mean (SD)	68.6 (24.23)	-14.3 (21.43)	74.8 (27.83)	-26.5 (25.77)	72.1 (25.44)	-29.4 (26.05)	73.5 (26.65)	-27.9 (25.90)	72.2 (26.08)	-24.3 (25.48)
	Median	65.0	-13.0	69.0	-28.0	67.0	-32.5	69.0	-30.0	67.0	-25.0
	Min, Max	34, 137	-62, 47	30, 158	-89, 32	30, 136	-92, 36	30, 158	-92, 36	30, 158	-92, 47

Sex: Female		PLCB-to-FLEX DOSE (N = 46)		40MG-to-FLEX DOSE (N = 80)		80MG-to-FLEX DOSE (N = 79)		Active-to-FLEX DOSE (N = 159)		Overall-to-FLEX DOSE (N = 205)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	46		80		79		159		205	
	Mean (SD)	87.1 (21.41)		102.1 (17.23)		101.6 (15.49)		101.8 (16.34)		98.5 (18.60)	

Sex: Female		PLCB-to-FLEX DOSE (N = 46)		40MG-to-FLEX DOSE (N = 80)		80MG-to-FLEX DOSE (N = 79)		Active-to-FLEX DOSE (N = 159)		Overall-to-FLEX DOSE (N = 205)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	85.5		98.0		99.0		98.0		96.0	
	Min, Max	46, 148		80, 157		80, 168		80, 168		46, 168	
On-treatment Week 1	n	46	46	80	80	78	78	158	158	204	204
	Mean (SD)	81.2 (20.26)	-5.8 (9.07)	98.7 (18.52)	-3.4 (9.36)	93.2 (17.67)	-8.3 (12.83)	96.0 (18.26)	-5.8 (11.45)	92.7 (19.68)	-5.8 (10.94)
	Median	76.0	-4.5	96.5	-3.0	92.0	-6.0	94.0	-4.0	92.0	-4.0
	Min, Max	41, 144	-40, 18	71, 154	-24, 29	59, 168	-71, 15	59, 168	-71, 29	41, 168	-71, 29
On-treatment Week 2	n	46	46	71	71	74	74	145	145	191	191
	Mean (SD)	78.3 (19.42)	-8.8 (10.87)	92.6 (20.20)	-9.4 (12.98)	87.9 (20.46)	-13.8 (17.74)	90.2 (20.40)	-11.6 (15.70)	87.3 (20.76)	-11.0 (14.71)
	Median	74.5	-6.5	90.0	-8.0	88.0	-10.0	88.0	-9.0	86.0	-8.0
	Min, Max	39, 129	-39, 21	58, 162	-38, 42	36, 167	-105, 23	36, 167	-105, 42	36, 167	-105, 42
On-treatment Week 4	n	46	46	63	63	72	72	135	135	181	181
	Mean (SD)	76.8 (21.12)	-10.3 (17.29)	85.3 (18.12)	-16.0 (12.94)	81.8 (21.40)	-19.7 (19.28)	83.4 (19.94)	-18.0 (16.67)	81.7 (20.40)	-16.0 (17.11)
	Median	72.0	-7.5	83.0	-16.0	84.5	-15.0	84.0	-15.0	82.0	-14.0
	Min, Max	43, 129	-55, 37	48, 147	-61, 9	38, 146	-105, 13	38, 147	-105, 13	38, 147	-105, 37
On-treatment Week 6	n			57	57	70	70	127	127	127	127
	Mean (SD)			82.3 (19.08)	-17.5 (15.40)	78.6 (21.55)	-23.0 (21.00)	80.3 (20.48)	-20.5 (18.82)	80.3 (20.48)	-20.5 (18.82)
	Median			79.0	-16.0	81.5	-19.0	80.0	-18.0	80.0	-18.0
	Min, Max			41, 146	-67, 14	34, 125	-115, 12	34, 146	-115, 14	34, 146	-115, 14

Sex: Female		PLCB-to-FLEX DOSE (N = 46)		40MG-to-FLEX DOSE (N = 80)		80MG-to-FLEX DOSE (N = 79)		Active-to-FLEX DOSE (N = 159)		Overall-to-FLEX DOSE (N = 205)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 7	n			50	50	67	67	117	117	117	117
	Mean (SD)			78.5 (19.98)	-21.9 (17.97)	79.3 (22.02)	-22.5 (20.50)	78.9 (21.08)	-22.2 (19.38)	78.9 (21.08)	-22.2 (19.38)
	Median			76.0	-18.5	83.0	-17.0	79.0	-18.0	79.0	-18.0
	Min, Max			41, 150	-77, 21	34, 123	-115, 13	34, 150	-115, 21	34, 150	-115, 21
On-treatment Week 8	n	41	41	47	47	65	65	112	112	153	153
	Mean (SD)	73.5 (24.95)	-13.5 (24.44)	78.2 (21.22)	-21.8 (18.36)	77.0 (20.94)	-24.8 (21.21)	77.5 (20.97)	-23.5 (20.03)	76.5 (22.09)	-20.8 (21.68)
	Median	68.0	-11.0	73.0	-22.0	80.0	-20.0	77.5	-20.0	76.0	-19.0
	Min, Max	34, 133	-66, 53	42, 161	-77, 19	34, 112	-115, 13	34, 161	-115, 19	34, 161	-115, 53
On-treatment Week 10	n			44	44	61	61	105	105	105	105
	Mean (SD)			76.5 (21.76)	-23.7 (20.12)	75.7 (21.46)	-26.7 (21.55)	76.0 (21.49)	-25.4 (20.92)	76.0 (21.49)	-25.4 (20.92)
	Median			71.0	-24.0	75.0	-22.0	74.0	-23.0	74.0	-23.0
	Min, Max			42, 167	-94, 21	34, 115	-115, 18	34, 167	-115, 21	34, 167	-115, 21
On-treatment Week 12	n	33	33							33	33
	Mean (SD)	68.5 (23.00)	-18.0 (21.95)							68.5 (23.00)	-18.0 (21.95)
	Median	64.0	-11.0							64.0	-11.0
	Min, Max	36, 127	-66, 16							36, 127	-66, 16

Sex: Female		PLCB-to-FLEX DOSE (N = 46)		40MG-to-FLEX DOSE (N = 80)		80MG-to-FLEX DOSE (N = 79)		Active-to-FLEX DOSE (N = 159)		Overall-to-FLEX DOSE (N = 205)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 14	n			43	43	61	61	104	104	104	104
	Mean (SD)			73.3 (17.16)	-26.0 (20.38)	73.4 (21.79)	-29.0 (22.47)	73.4 (19.92)	-27.7 (21.58)	73.4 (19.92)	-27.7 (21.58)
	Median			73.0	-27.0	72.0	-29.0	72.5	-27.0	72.5	-27.0
	Min, Max			41, 108	-107, 4	33, 121	-116, 10	33, 121	-116, 10	33, 121	-116, 10
On-treatment Week 16	n	31	31							31	31
	Mean (SD)	68.0 (22.13)	-19.2 (20.73)							68.0 (22.13)	-19.2 (20.73)
	Median	65.0	-16.0							65.0	-16.0
	Min, Max	33, 122	-60, 16							33, 122	-60, 16
On-treatment Week 18	n			36	36	53	53	89	89	89	89
	Mean (SD)			68.0 (16.89)	-32.4 (18.69)	68.7 (20.92)	-33.4 (22.56)	68.4 (19.29)	-33.0 (20.98)	68.4 (19.29)	-33.0 (20.98)
	Median			65.0	-32.0	67.0	-31.0	66.0	-31.0	66.0	-31.0
	Min, Max			43, 105	-99, 2	33, 111	-116, 11	33, 111	-116, 11	33, 111	-116, 11
On-treatment Week 20	n	30	30							30	30
	Mean (SD)	65.1 (23.06)	-22.7 (21.95)							65.1 (23.06)	-22.7 (21.95)
	Median	63.5	-20.0							63.5	-20.0
	Min, Max	32, 130	-66, 19							32, 130	-66, 19
On-treatment Week 22	n			35	35	50	50	85	85	85	85

Sex: Female		PLCB-to-FLEX DOSE (N = 46)		40MG-to-FLEX DOSE (N = 80)		80MG-to-FLEX DOSE (N = 79)		Active-to-FLEX DOSE (N = 159)		Overall-to-FLEX DOSE (N = 205)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			65.7 (16.78)	-33.8 (17.77)	67.9 (20.62)	-34.2 (21.86)	67.0 (19.06)	-34.1 (20.16)	67.0 (19.06)	-34.1 (20.16)
	Median			64.0	-33.0	65.0	-32.0	65.0	-32.0	65.0	-32.0
	Min, Max			42, 105	-93, 2	32, 110	-117, 3	32, 110	-117, 3	32, 110	-117, 3
On-treatment Week 24	n	29	29							29	29
	Mean (SD)	63.1 (25.08)	-25.2 (23.80)							63.1 (25.08)	-25.2 (23.80)
	Median	56.0	-22.0							56.0	-22.0
	Min, Max	31, 130	-69, 15							31, 130	-69, 15
On-treatment Week 26	n			32	32	50	50	82	82	82	82
	Mean (SD)			63.8 (19.65)	-36.0 (21.39)	67.2 (23.47)	-35.0 (24.00)	65.9 (21.99)	-35.4 (22.88)	65.9 (21.99)	-35.4 (22.88)
	Median			59.0	-35.5	65.5	-33.0	62.5	-33.5	62.5	-33.5
	Min, Max			37, 114	-99, 6	31, 118	-118, 20	31, 118	-118, 20	31, 118	-118, 20
On-treatment Week 28	n	26	26							26	26
	Mean (SD)	63.8 (26.30)	-25.9 (25.72)							63.8 (26.30)	-25.9 (25.72)
	Median	55.5	-22.0							55.5	-22.0
	Min, Max	36, 130	-73, 15							36, 130	-73, 15
On-treatment Week 30	n			30	30	47	47	77	77	77	77
	Mean (SD)			61.2 (17.76)	-38.4 (21.17)	66.1 (23.96)	-35.9 (25.75)	64.2 (21.76)	-36.9 (23.95)	64.2 (21.76)	-36.9 (23.95)
	Median			57.5	-38.0	64.0	-37.0	60.0	-37.0	60.0	-37.0

Sex: Female		PLCB-to-FLEX DOSE (N = 46)		40MG-to-FLEX DOSE (N = 80)		80MG-to-FLEX DOSE (N = 79)		Active-to-FLEX DOSE (N = 159)		Overall-to-FLEX DOSE (N = 205)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			35, 105	-103, 2	31, 125	-118, 34	31, 125	-118, 34	31, 125	-118, 34
On-treatment Week 34	n			30	30	48	48	78	78	78	78
	Mean (SD)			61.9 (17.73)	-37.8 (20.26)	62.5 (22.41)	-39.6 (23.70)	62.2 (20.62)	-38.9 (22.33)	62.2 (20.62)	-38.9 (22.33)
	Median			61.5	-35.5	61.0	-39.5	61.5	-38.0	61.5	-38.0
	Min, Max			34, 105	-96, 2	31, 117	-118, 10	31, 117	-118, 10	31, 117	-118, 10
On-treatment Week 36	n	6	6							6	6
	Mean (SD)	70.7 (29.68)	-22.8 (30.90)							70.7 (29.68)	-22.8 (30.90)
	Median	72.0	-13.5							72.0	-13.5
	Min, Max	36, 111	-67, 11							36, 111	-67, 11
On-treatment Week 42	n			10	10	12	12	22	22	22	22
	Mean (SD)			76.5 (20.04)	-29.1 (27.92)	83.3 (24.01)	-29.4 (31.95)	80.2 (22.04)	-29.3 (29.47)	80.2 (22.04)	-29.3 (29.47)
	Median			74.5	-22.5	85.5	-25.5	76.5	-24.5	76.5	-24.5
	Min, Max			34, 105	-94, 2	31, 111	-118, 2	31, 111	-118, 2	31, 111	-118, 2
On-treatment Week 44	n	5	5							5	5
	Mean (SD)	63.2 (26.71)	-29.0 (32.76)							63.2 (26.71)	-29.0 (32.76)
	Median	66.0	-22.0							66.0	-22.0
	Min, Max	35, 93	-72, 4							35, 93	-72, 4

Sex: Female		PLCB-to-FLEX DOSE (N = 46)		40MG-to-FLEX DOSE (N = 80)		80MG-to-FLEX DOSE (N = 79)		Active-to-FLEX DOSE (N = 159)		Overall-to-FLEX DOSE (N = 205)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 50	n			10	10	10	10	20	20	20	20
	Mean (SD)			76.3 (19.44)	-29.3 (26.55)	86.0 (27.37)	-26.8 (35.40)	81.2 (23.64)	-28.1 (30.48)	81.2 (23.64)	-28.1 (30.48)
	Median			74.0	-24.0	93.0	-19.0	79.5	-22.0	79.5	-22.0
	Min, Max			35, 105	-90, 2	31, 121	-118, 4	31, 121	-118, 4	31, 121	-118, 4
On-treatment Week 52	n	5	5							5	5
	Mean (SD)	62.0 (26.68)	-30.2 (31.32)							62.0 (26.68)	-30.2 (31.32)
	Median	60.0	-22.0							60.0	-22.0
	Min, Max	35, 93	-72, -2							35, 93	-72, -2
On-treatment Week 58	n			8	8	7	7	15	15	15	15
	Mean (SD)			72.5 (21.78)	-35.3 (32.15)	79.6 (29.85)	-36.4 (38.90)	75.8 (25.15)	-35.8 (34.14)	75.8 (25.15)	-35.8 (34.14)
	Median			74.5	-28.0	81.0	-26.0	76.0	-26.0	76.0	-26.0
	Min, Max			33, 105	-102, 2	31, 114	-118, 1	31, 114	-118, 2	31, 114	-118, 2
On-treatment (LOCF)	n	46	46	80	80	78	78	158	158	204	204
	Mean (SD)	71.9 (28.00)	-15.2 (29.02)	84.6 (28.97)	-17.5 (26.28)	73.6 (26.74)	-27.9 (26.97)	79.1 (28.34)	-22.7 (27.05)	77.5 (28.36)	-21.0 (27.61)
	Median	66.5	-11.5	80.5	-16.0	71.5	-25.5	77.5	-20.0	74.5	-19.0
	Min, Max	31, 133	-73, 53	33, 167	-102, 42	31, 125	-118, 34	31, 167	-118, 42	31, 167	-118, 53

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline values are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-37　PANSS 合計スコア変化量

（20 試験：ロナセンテープ貼付期　Open 52 週、高齢者/非高齢者別）

DSP-5423P Dosed Population

Age: <65		PLCB-to-FLEX DOSE (N = 123)		40MG-to-FLEX DOSE (N = 185)		80MG-to-FLEX DOSE (N = 182)		Active-to-FLEX DOSE (N = 367)		Overall-to-FLEX DOSE (N = 490)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	123		185		182		367		490	
	Mean (SD)	84.6 (20.26)		101.7 (15.51)		101.3 (14.44)		101.5 (14.97)		97.3 (18.00)	
	Median	84.0		99.0		99.0		99.0		97.0	
	Min, Max	38, 148		80, 157		80, 168		80, 168		38, 168	
On-treatment Week 1	n	121	121	185	185	180	180	365	365	486	486
	Mean (SD)	80.7 (20.49)	-3.6 (7.77)	95.5 (18.11)	-6.2 (10.67)	93.8 (17.29)	-7.5 (12.57)	94.6 (17.71)	-6.8 (11.65)	91.2 (19.38)	-6.0 (10.90)
	Median	78.0	-3.0	93.0	-5.0	92.5	-6.0	93.0	-5.0	90.5	-4.0
	Min, Max	37, 144	-40, 18	45, 154	-41, 36	56, 168	-71, 36	45, 168	-71, 36	37, 168	-71, 36
On-treatment Week 2	n	122	122	168	168	172	172	340	340	462	462
	Mean (SD)	77.7 (19.83)	-6.7 (11.08)	88.8 (18.81)	-12.4 (14.16)	87.4 (18.41)	-13.9 (16.07)	88.1 (18.59)	-13.2 (15.15)	85.3 (19.45)	-11.5 (14.46)
	Median	75.0	-6.0	88.0	-11.5	88.0	-11.0	88.0	-11.0	85.0	-9.0
	Min, Max	38, 141	-39, 21	36, 157	-50, 42	36, 167	-105, 23	36, 167	-105, 42	36, 167	-105, 42
On-treatment Week 4	n	119	119	158	158	163	163	321	321	440	440
	Mean (SD)	74.9 (19.69)	-9.5 (13.51)	83.4 (18.96)	-17.7 (14.63)	81.2 (19.48)	-20.0 (18.20)	82.3 (19.23)	-18.9 (16.56)	80.3 (19.61)	-16.4 (16.31)
	Median	73.0	-9.0	82.0	-16.0	83.0	-17.0	83.0	-16.0	80.0	-14.0
	Min, Max	38, 129	-55, 37	34, 147	-63, 21	38, 146	-105, 17	34, 147	-105, 21	34, 147	-105, 37

Age: <65		PLCB-to-FLEX DOSE (N = 123)		40MG-to-FLEX DOSE (N = 185)		80MG-to-FLEX DOSE (N = 182)		Active-to-FLEX DOSE (N = 367)		Overall-to-FLEX DOSE (N = 490)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 6	n			147	147	155	155	302	302	302	302
	Mean (SD)			80.4 (19.09)	-20.1 (16.59)	78.1 (20.79)	-22.9 (20.27)	79.2 (19.98)	-21.5 (18.60)	79.2 (19.98)	-21.5 (18.60)
	Median			80.0	-18.0	81.0	-19.0	80.0	-19.0	80.0	-19.0
	Min, Max			34, 146	-73, 14	34, 136	-115, 12	34, 146	-115, 14	34, 146	-115, 14
On-treatment Week 7	n			134	134	147	147	281	281	281	281
	Mean (SD)			76.5 (19.70)	-24.4 (17.34)	76.6 (20.79)	-24.5 (20.97)	76.6 (20.24)	-24.4 (19.29)	76.6 (20.24)	-24.4 (19.29)
	Median			75.0	-24.0	79.0	-20.0	76.0	-22.0	76.0	-22.0
	Min, Max			32, 150	-77, 21	32, 139	-115, 24	32, 150	-115, 24	32, 150	-115, 24
On-treatment Week 8	n	111	111	129	129	146	146	275	275	386	386
	Mean (SD)	71.2 (21.61)	-13.3 (18.92)	75.2 (20.47)	-25.6 (18.24)	74.2 (20.25)	-26.8 (21.22)	74.7 (20.33)	-26.2 (19.85)	73.7 (20.74)	-22.5 (20.43)
	Median	69.0	-12.0	71.0	-25.0	76.0	-22.0	74.0	-24.0	72.0	-21.0
	Min, Max	34, 133	-66, 53	34, 161	-77, 19	30, 130	-115, 15	30, 161	-115, 19	30, 161	-115, 53
On-treatment Week 10	n			126	126	140	140	266	266	266	266
	Mean (SD)			73.2 (20.52)	-27.7 (18.98)	72.0 (20.50)	-29.3 (21.98)	72.5 (20.48)	-28.5 (20.59)	72.5 (20.48)	-28.5 (20.59)
	Median			69.0	-26.0	72.0	-26.0	71.0	-26.0	71.0	-26.0
	Min, Max			32, 167	-94, 21	30, 122	-115, 18	30, 167	-115, 21	30, 167	-115, 21

Age: <65		PLCB-to-FLEX DOSE (N = 123)		40MG-to-FLEX DOSE (N = 185)		80MG-to-FLEX DOSE (N = 182)		Active-to-FLEX DOSE (N = 367)		Overall-to-FLEX DOSE (N = 490)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 12	n	99	99							99	99
	Mean (SD)	68.0 (20.32)	-15.9 (18.70)							68.0 (20.32)	-15.9 (18.70)
	Median	66.0	-11.0							66.0	-11.0
	Min, Max	32, 137	-66, 33							32, 137	-66, 33
On-treatment Week 14	n			119	119	136	136	255	255	255	255
	Mean (SD)			70.4 (21.17)	-30.1 (20.94)	70.0 (19.87)	-30.7 (21.24)	70.2 (20.45)	-30.4 (21.06)	70.2 (20.45)	-30.4 (21.06)
	Median			67.0	-29.0	71.0	-29.0	70.0	-29.0	70.0	-29.0
	Min, Max			30, 158	-107, 32	30, 121	-116, 10	30, 158	-116, 32	30, 158	-116, 32
On-treatment Week 16	n	95	95							95	95
	Mean (SD)	65.4 (18.41)	-18.3 (18.29)							65.4 (18.41)	-18.3 (18.29)
	Median	63.0	-16.0							63.0	-16.0
	Min, Max	31, 122	-64, 23							31, 122	-64, 23
On-treatment Week 18	n			103	103	121	121	224	224	224	224
	Mean (SD)			65.0 (17.28)	-34.8 (18.45)	66.8 (18.77)	-33.8 (21.39)	66.0 (18.08)	-34.3 (20.05)	66.0 (18.08)	-34.3 (20.05)
	Median			64.0	-35.0	66.0	-31.0	65.5	-33.0	65.5	-33.0
	Min, Max			30, 106	-99, 7	30, 111	-116, 11	30, 111	-116, 11	30, 111	-116, 11
On-treatment Week 20	n	86	86							86	86

Age: <65		PLCB-to-FLEX DOSE (N = 123)		40MG-to-FLEX DOSE (N = 185)		80MG-to-FLEX DOSE (N = 182)		Active-to-FLEX DOSE (N = 367)		Overall-to-FLEX DOSE (N = 490)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	64.3 (20.21)	-19.8 (20.98)							64.3 (20.21)	-19.8 (20.98)
	Median	63.0	-20.0							63.0	-20.0
	Min, Max	32, 130	-71, 47							32, 130	-71, 47
On-treatment Week 22	n			101	101	117	117	218	218	218	218
	Mean (SD)			62.9 (16.83)	-36.3 (18.34)	65.2 (18.79)	-35.5 (21.49)	64.1 (17.91)	-35.9 (20.05)	64.1 (17.91)	-35.9 (20.05)
	Median			62.0	-37.0	65.0	-33.0	64.0	-34.0	64.0	-34.0
	Min, Max			30, 104	-93, 14	32, 110	-117, 3	30, 110	-117, 14	30, 110	-117, 14
On-treatment Week 24	n	85	85							85	85
	Mean (SD)	62.6 (20.61)	-21.8 (20.50)							62.6 (20.61)	-21.8 (20.50)
	Median	60.0	-18.0							60.0	-18.0
	Min, Max	31, 130	-69, 32							31, 130	-69, 32
On-treatment Week 26	n			94	94	112	112	206	206	206	206
	Mean (SD)			61.5 (18.29)	-38.5 (19.12)	63.5 (20.22)	-37.4 (22.47)	62.6 (19.34)	-37.9 (20.96)	62.6 (19.34)	-37.9 (20.96)
	Median			58.0	-40.0	64.0	-36.0	60.0	-37.0	60.0	-37.0
	Min, Max			30, 114	-99, 6	31, 118	-118, 20	30, 118	-118, 20	30, 118	-118, 20
On-treatment Week 28	n	79	79							79	79
	Mean (SD)	61.2 (20.75)	-24.2 (20.41)							61.2 (20.75)	-24.2 (20.41)
	Median	59.0	-22.0							59.0	-22.0

Age: <65		PLCB-to-FLEX DOSE (N = 123)		40MG-to-FLEX DOSE (N = 185)		80MG-to-FLEX DOSE (N = 182)		Active-to-FLEX DOSE (N = 367)		Overall-to-FLEX DOSE (N = 490)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	34, 130	-73, 15							34, 130	-73, 15
On-treatment Week 30	n			87	87	108	108	195	195	195	195
	Mean (SD)			58.8 (16.79)	-40.1 (18.84)	62.4 (20.52)	-38.5 (23.23)	60.8 (18.98)	-39.2 (21.35)	60.8 (18.98)	-39.2 (21.35)
	Median			58.0	-41.0	63.0	-37.0	60.0	-38.0	60.0	-38.0
	Min, Max			30, 108	-103, 6	30, 125	-118, 34	30, 125	-118, 34	30, 125	-118, 34
On-treatment Week 34	n			86	86	109	109	195	195	195	195
	Mean (SD)			58.5 (16.94)	-40.5 (19.21)	59.7 (19.53)	-41.2 (21.66)	59.1 (18.40)	-40.9 (20.57)	59.1 (18.40)	-40.9 (20.57)
	Median			58.0	-41.0	60.0	-39.0	59.0	-40.0	59.0	-40.0
	Min, Max			30, 112	-96, 10	30, 117	-118, 10	30, 117	-118, 10	30, 117	-118, 10
On-treatment Week 36	n	13	13							13	13
	Mean (SD)	78.5 (27.91)	-16.3 (24.67)							78.5 (27.91)	-16.3 (24.67)
	Median	85.0	-12.0							85.0	-12.0
	Min, Max	36, 133	-67, 23							36, 133	-67, 23
On-treatment Week 42	n			15	15	22	22	37	37	37	37
	Mean (SD)			76.6 (15.46)	-28.1 (25.00)	77.8 (20.76)	-27.6 (25.86)	77.3 (18.56)	-27.8 (25.17)	77.3 (18.56)	-27.8 (25.17)
	Median			74.0	-25.0	75.5	-29.5	74.0	-27.0	74.0	-27.0
	Min, Max			58, 112	-94, 10	31, 111	-118, 2	31, 112	-118, 10	31, 112	-118, 10

Age: <65		PLCB-to-FLEX DOSE (N = 123)		40MG-to-FLEX DOSE (N = 185)		80MG-to-FLEX DOSE (N = 182)		Active-to-FLEX DOSE (N = 367)		Overall-to-FLEX DOSE (N = 490)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 44	n	11	11							11	11
	Mean (SD)	70.3 (22.97)	-22.7 (23.00)							70.3 (22.97)	-22.7 (23.00)
	Median	73.0	-13.0							73.0	-13.0
	Min, Max	35, 100	-72, 1							35, 100	-72, 1
On-treatment Week 50	n			15	15	21	21	36	36	36	36
	Mean (SD)			77.1 (17.97)	-27.6 (26.87)	78.4 (22.19)	-27.3 (27.01)	77.8 (20.27)	-27.4 (26.57)	77.8 (20.27)	-27.4 (26.57)
	Median			73.0	-25.0	77.0	-21.0	75.0	-24.0	75.0	-24.0
	Min, Max			53, 120	-90, 18	31, 121	-118, 4	31, 121	-118, 18	31, 121	-118, 18
On-treatment Week 52	n	9	9							9	9
	Mean (SD)	68.9 (25.78)	-25.1 (26.29)							68.9 (25.78)	-25.1 (26.29)
	Median	72.0	-22.0							72.0	-22.0
	Min, Max	35, 103	-72, 5							35, 103	-72, 5
On-treatment Week 58	n			12	12	18	18	30	30	30	30
	Mean (SD)			69.9 (16.84)	-36.3 (29.49)	74.6 (20.47)	-31.2 (27.04)	72.7 (18.94)	-33.2 (27.65)	72.7 (18.94)	-33.2 (27.65)
	Median			71.0	-30.0	74.5	-33.5	73.5	-33.0	73.5	-33.0
	Min, Max			42, 92	-102, 9	31, 114	-118, 1	31, 114	-118, 9	31, 114	-118, 9
On-treatment (LOCF)	n	122	122	185	185	180	180	365	365	487	487

Age: <65		PLCB-to-FLEX DOSE (N = 123)		40MG-to-FLEX DOSE (N = 185)		80MG-to-FLEX DOSE (N = 182)		Active-to-FLEX DOSE (N = 367)		Overall-to-FLEX DOSE (N = 490)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	68.8 (25.94)	-15.5 (24.76)	78.1 (28.41)	-23.6 (26.27)	72.2 (26.28)	-29.1 (26.80)	75.2 (27.50)	-26.3 (26.64)	73.6 (27.23)	-23.6 (26.57)
	Median	65.0	-13.0	75.0	-23.0	66.5	-30.0	71.0	-26.0	69.0	-22.0
	Min, Max	31, 137	-73, 53	30, 167	-102, 42	30, 136	-118, 36	30, 167	-118, 42	30, 167	-118, 53

Age: >=65		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 11)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 23)		Overall-to-FLEX DOSE (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	8		11		12		23		31	
	Mean (SD)	84.8 (16.10)		100.4 (16.98)		104.8 (18.55)		102.7 (17.56)		98.1 (18.72)	
	Median	90.0		99.0		103.5		99.0		95.0	
	Min, Max	62, 104		82, 143		83, 130		82, 143		62, 143	
On-treatment Week 1	n	8	8	11	11	12	12	23	23	31	31
	Mean (SD)	83.9 (15.63)	-0.9 (1.55)	99.4 (19.56)	-1.0 (5.59)	96.9 (14.70)	-7.9 (8.78)	98.1 (16.84)	-4.6 (8.08)	94.4 (17.46)	-3.6 (7.15)
	Median	89.0	-0.5	97.0	0.0	94.5	-4.0	97.0	-1.0	95.0	-1.0
	Min, Max	60, 100	-4, 1	76, 152	-14, 9	77, 125	-24, 0	76, 152	-24, 9	60, 152	-24, 9
On-treatment Week 2	n	7	7	11	11	11	11	22	22	29	29
	Mean (SD)	85.3 (15.29)	-1.3 (2.06)	99.4 (23.41)	-1.0 (10.40)	90.1 (18.68)	-16.6 (19.20)	94.7 (21.20)	-8.8 (17.06)	92.4 (20.10)	-7.0 (15.16)
	Median	93.0	-2.0	98.0	0.0	88.0	-9.0	97.0	-5.0	94.0	-3.0
	Min, Max	60, 101	-3, 3	73, 162	-19, 19	62, 125	-62, 7	62, 162	-62, 19	60, 162	-62, 19

Age: >=65		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 11)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 23)		Overall-to-FLEX DOSE (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 4	n	6	6	9	9	11	11	20	20	26	26
	Mean (SD)	85.2 (15.74)	-1.7 (3.83)	90.2 (11.11)	-5.6 (12.42)	87.5 (18.50)	-19.2 (19.00)	88.8 (15.29)	-13.1 (17.42)	87.9 (15.15)	-10.4 (16.04)
	Median	93.5	-2.5	95.0	0.0	82.0	-12.0	83.5	-8.5	88.0	-5.0
	Min, Max	60, 98	-6, 5	71, 103	-31, 6	55, 125	-51, 13	55, 125	-51, 13	55, 125	-51, 13
On-treatment Week 6	n			9	9	11	11	20	20	20	20
	Mean (SD)			89.2 (12.66)	-6.6 (14.81)	87.1 (18.96)	-19.6 (19.51)	88.1 (16.06)	-13.8 (18.36)	88.1 (16.06)	-13.8 (18.36)
	Median			95.0	0.0	79.0	-13.0	85.0	-9.0	85.0	-9.0
	Min, Max			66, 103	-37, 6	58, 125	-54, 12	58, 125	-54, 12	58, 125	-54, 12
On-treatment Week 7	n			8	8	9	9	17	17	17	17
	Mean (SD)			87.9 (12.89)	-9.6 (15.39)	86.6 (23.28)	-21.1 (22.20)	87.2 (18.55)	-15.7 (19.62)	87.2 (18.55)	-15.7 (19.62)
	Median			90.0	-3.0	83.0	-12.0	85.0	-11.0	85.0	-11.0
	Min, Max			70, 103	-38, 6	43, 123	-55, 13	43, 123	-55, 13	43, 123	-55, 13
On-treatment Week 8	n	6	6	8	8	8	8	16	16	22	22
	Mean (SD)	85.3 (16.79)	-1.5 (8.73)	86.4 (13.20)	-11.1 (15.64)	87.6 (17.00)	-23.1 (23.48)	87.0 (14.72)	-17.1 (20.24)	86.5 (14.91)	-12.9 (19.02)
	Median	93.5	-3.5	85.0	-4.5	81.5	-16.0	81.5	-11.5	87.0	-8.5
	Min, Max	53, 96	-9, 15	66, 103	-35, 9	70, 112	-55, 13	66, 112	-55, 13	53, 112	-55, 15
On-treatment Week 10	n			8	8	6	6	14	14	14	14

Age: >=65		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 11)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 23)		Overall-to-FLEX DOSE (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			86.6 (14.76)	-10.9 (16.92)	84.8 (15.12)	-25.8 (14.92)	85.9 (14.36)	-17.3 (17.29)	85.9 (14.36)	-17.3 (17.29)
	Median			86.0	-4.0	83.0	-22.0	83.0	-17.5	83.0	-17.5
	Min, Max			62, 103	-33, 12	67, 103	-46, -10	62, 103	-46, 12	62, 103	-46, 12
On-treatment Week 12	n	5	5							5	5
	Mean (SD)	83.2 (17.37)	-2.0 (9.67)							83.2 (17.37)	-2.0 (9.67)
	Median	90.0	-5.0							90.0	-5.0
	Min, Max	54, 96	-8, 15							54, 96	-8, 15
On-treatment Week 14	n			8	8	6	6	14	14	14	14
	Mean (SD)			85.3 (15.50)	-12.3 (18.06)	88.0 (14.81)	-24.8 (13.56)	86.4 (14.68)	-17.6 (16.97)	86.4 (14.68)	-17.6 (16.97)
	Median			86.0	-4.5	88.0	-22.5	87.5	-17.0	87.5	-17.0
	Min, Max			61, 103	-35, 10	66, 103	-46, -11	61, 103	-46, 10	61, 103	-46, 10
On-treatment Week 16	n	4	4							4	4
	Mean (SD)	80.0 (15.51)	-1.8 (8.34)							80.0 (15.51)	-1.8 (8.34)
	Median	82.5	-4.0							82.5	-4.0
	Min, Max	60, 95	-9, 10							60, 95	-9, 10
On-treatment Week 18	n			6	6	5	5	11	11	11	11
	Mean (SD)			81.3 (21.73)	-19.3 (22.77)	84.8 (18.82)	-24.6 (18.96)	82.9 (19.52)	-21.7 (20.26)	82.9 (19.52)	-21.7 (20.26)
	Median			86.0	-21.0	77.0	-21.0	77.0	-21.0	77.0	-21.0

Age: >=65		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 11)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 23)		Overall-to-FLEX DOSE (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			49, 105	-43, 7	68, 107	-57, -8	49, 107	-57, 7	49, 107	-57, 7
On-treatment Week 20	n	4	4							4	4
	Mean (SD)	83.0 (15.43)	1.3 (14.97)							83.0 (15.43)	1.3 (14.97)
	Median	89.5	-3.5							89.5	-3.5
	Min, Max	60, 93	-11, 23							60, 93	-11, 23
On-treatment Week 22	n			6	6	5	5	11	11	11	11
	Mean (SD)			83.2 (20.23)	-17.5 (22.76)	89.0 (17.42)	-20.4 (8.53)	85.8 (18.31)	-18.8 (17.04)	85.8 (18.31)	-18.8 (17.04)
	Median			85.5	-19.5	95.0	-23.0	95.0	-23.0	95.0	-23.0
	Min, Max			58, 105	-40, 11	65, 106	-31, -9	58, 106	-40, 11	58, 106	-40, 11
On-treatment Week 24	n	4	4							4	4
	Mean (SD)	79.5 (17.29)	-2.3 (9.43)							79.5 (17.29)	-2.3 (9.43)
	Median	84.5	-4.5							84.5	-4.5
	Min, Max	56, 93	-11, 11							56, 93	-11, 11
On-treatment Week 26	n			5	5	5	5	10	10	10	10
	Mean (SD)			75.2 (26.96)	-27.8 (24.18)	90.8 (19.21)	-18.6 (6.27)	83.0 (23.55)	-23.2 (17.34)	83.0 (23.55)	-23.2 (17.34)
	Median			74.0	-38.0	101.0	-19.0	86.5	-21.5	86.5	-21.5
	Min, Max			37, 105	-55, 2	64, 107	-25, -10	37, 107	-55, 2	37, 107	-55, 2

Age: >=65		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 11)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 23)		Overall-to-FLEX DOSE (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 28	n	4	4							4	4
	Mean (SD)	81.3 (19.82)	-0.5 (14.39)							81.3 (19.82)	-0.5 (14.39)
	Median	89.5	-5.5							89.5	-5.5
	Min, Max	52, 94	-11, 20							52, 94	-11, 20
On-treatment Week 30	n			5	5	5	5	10	10	10	10
	Mean (SD)			74.0 (27.69)	-29.0 (25.41)	86.2 (18.13)	-23.2 (10.83)	80.1 (22.98)	-26.1 (18.66)	80.1 (22.98)	-26.1 (18.66)
	Median			68.0	-37.0	88.0	-24.0	82.0	-26.0	82.0	-26.0
	Min, Max			35, 105	-57, 2	61, 105	-38, -10	35, 105	-57, 2	35, 105	-57, 2
On-treatment Week 34	n			5	5	5	5	10	10	10	10
	Mean (SD)			73.2 (27.99)	-29.8 (25.81)	84.4 (18.41)	-25.0 (13.60)	78.8 (23.10)	-27.4 (19.61)	78.8 (23.10)	-27.4 (19.61)
	Median			68.0	-37.0	80.0	-24.0	77.5	-26.0	77.5	-26.0
	Min, Max			34, 105	-58, 2	61, 105	-46, -10	34, 105	-58, 2	34, 105	-58, 2
On-treatment Week 36	n	4	4							4	4
	Mean (SD)	79.8 (16.11)	-2.0 (8.60)							79.8 (16.11)	-2.0 (8.60)
	Median	83.5	-2.5							83.5	-2.5
	Min, Max	59, 93	-12, 9							59, 93	-12, 9
On-treatment Week 42	n			5	5	5	5	10	10	10	10

Age: >=65		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 11)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 23)		Overall-to-FLEX DOSE (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			73.4 (27.92)	-29.6 (25.64)	84.4 (18.68)	-25.0 (13.29)	78.9 (23.13)	-27.3 (19.40)	78.9 (23.13)	-27.3 (19.40)
	Median			68.0	-37.0	81.0	-24.0	78.0	-26.5	78.0	-26.5
	Min, Max			34, 105	-58, 2	60, 105	-45, -10	34, 105	-58, 2	34, 105	-58, 2
On-treatment Week 44	n	4	4							4	4
	Mean (SD)	82.0 (14.26)	0.3 (8.18)							82.0 (14.26)	0.3 (8.18)
	Median	83.5	2.0							83.5	2.0
	Min, Max	66, 95	-11, 8							66, 95	-11, 8
On-treatment Week 50	n			5	5	4	4	9	9	9	9
	Mean (SD)			74.6 (27.13)	-28.4 (24.70)	84.8 (22.01)	-20.5 (8.54)	79.1 (24.05)	-24.9 (18.70)	79.1 (24.05)	-24.9 (18.70)
	Median			73.0	-32.0	87.5	-21.0	74.0	-24.0	74.0	-24.0
	Min, Max			35, 105	-57, 2	59, 105	-30, -10	35, 105	-57, 2	35, 105	-57, 2
On-treatment Week 52	n	4	4							4	4
	Mean (SD)	81.5 (16.54)	-0.3 (8.66)							81.5 (16.54)	-0.3 (8.66)
	Median	85.5	-1.0							85.5	-1.0
	Min, Max	60, 95	-10, 11							60, 95	-10, 11
On-treatment Week 58	n			5	5	4	4	9	9	9	9
	Mean (SD)			74.8 (27.97)	-28.2 (25.29)	84.8 (21.79)	-20.5 (8.10)	79.2 (24.43)	-24.8 (19.00)	79.2 (24.43)	-24.8 (19.00)
	Median			74.0	-31.0	87.0	-21.5	74.0	-24.0	74.0	-24.0

Age: >=65		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 11)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 23)		Overall-to-FLEX DOSE (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			33, 105	-59, 2	60, 105	-29, -10	33, 105	-59, 2	33, 105	-59, 2
On-treatment (LOCF)	n	8	8	11	11	12	12	23	23	31	31
	Mean (SD)	84.0 (13.27)	-0.8 (5.82)	90.2 (31.32)	-10.2 (24.33)	80.7 (18.79)	-24.2 (18.92)	85.2 (25.42)	-17.5 (22.34)	84.9 (22.70)	-13.2 (20.72)
	Median	89.0	-0.5	94.0	-1.0	79.0	-26.5	84.0	-13.0	84.0	-5.0
	Min, Max	60, 95	-10, 11	33, 162	-59, 19	43, 105	-46, 13	33, 162	-59, 19	33, 162	-59, 19

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline values are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-38　PANSS 合計スコア変化量

（20 試験：ロナセンテープ貼付期　Open 52 週、入院/外来別）

DSP-5423P Dosed Population

Hospitalization Status: Inpatient		PLCB-to-FLEX DOSE (N = 127)		40MG-to-FLEX DOSE (N = 188)		80MG-to-FLEX DOSE (N = 189)		Active-to-FLEX DOSE (N = 377)		Overall-to-FLEX DOSE (N = 504)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	127		188		189		377		504	
	Mean (SD)	84.2 (20.07)		101.4 (15.77)		101.4 (14.36)		101.4 (15.06)		97.1 (18.07)	
	Median	84.0		98.0		99.0		99.0		96.0	
	Min, Max	38, 148		80, 157		80, 168		80, 168		38, 168	
On-treatment Week 1	n	125	125	188	188	187	187	375	375	500	500
	Mean (SD)	80.7 (20.39)	-3.2 (7.18)	95.5 (18.41)	-5.9 (10.67)	94.0 (17.18)	-7.4 (11.09)	94.8 (17.80)	-6.7 (10.89)	91.3 (19.45)	-5.8 (10.20)

Hospitalization Status: Inpatient		PLCB-to-FLEX DOSE (N = 127)		40MG-to-FLEX DOSE (N = 188)		80MG-to-FLEX DOSE (N = 189)		Active-to-FLEX DOSE (N = 377)		Overall-to-FLEX DOSE (N = 504)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	78.0	-2.0	93.0	-4.0	93.0	-6.0	93.0	-5.0	91.0	-4.0
	Min, Max	37, 144	-40, 18	45, 154	-41, 36	56, 168	-56, 20	45, 168	-56, 36	37, 168	-56, 36
On-treatment Week 2	n	125	125	172	172	179	179	351	351	476	476
	Mean (SD)	77.8 (19.80)	-6.3 (10.75)	89.4 (19.36)	-11.5 (14.28)	87.9 (18.27)	-13.6 (14.84)	88.6 (18.80)	-12.5 (14.58)	85.8 (19.63)	-10.9 (13.95)
	Median	75.0	-6.0	88.5	-10.0	88.0	-11.0	88.0	-10.0	85.0	-9.0
	Min, Max	38, 141	-39, 21	36, 162	-50, 42	36, 167	-70, 23	36, 167	-70, 42	36, 167	-70, 42
On-treatment Week 4	n	121	121	160	160	170	170	330	330	451	451
	Mean (SD)	74.9 (19.54)	-9.2 (13.27)	83.5 (18.82)	-17.1 (14.93)	81.9 (19.39)	-19.6 (17.00)	82.7 (19.10)	-18.4 (16.05)	80.6 (19.51)	-15.9 (15.87)
	Median	72.0	-8.0	82.5	-16.0	83.0	-16.5	83.0	-16.0	80.0	-14.0
	Min, Max	38, 129	-55, 37	34, 147	-63, 21	38, 146	-72, 17	34, 147	-72, 21	34, 147	-72, 37
On-treatment Week 6	n			150	150	162	162	312	312	312	312
	Mean (SD)			80.3 (18.85)	-19.5 (16.74)	78.9 (20.62)	-22.3 (18.84)	79.6 (19.77)	-21.0 (17.89)	79.6 (19.77)	-21.0 (17.89)
	Median			80.0	-18.0	81.0	-19.0	80.0	-18.0	80.0	-18.0
	Min, Max			34, 146	-73, 10	36, 136	-80, 12	34, 146	-80, 12	34, 146	-80, 12
On-treatment Week 7	n			136	136	152	152	288	288	288	288
	Mean (SD)			76.5 (19.35)	-24.0 (17.32)	77.5 (20.96)	-23.9 (19.83)	77.0 (20.19)	-23.9 (18.66)	77.0 (20.19)	-23.9 (18.66)
	Median			75.0	-24.0	79.0	-20.0	77.0	-22.0	77.0	-22.0
	Min, Max			32, 150	-77, 7	32, 139	-84, 24	32, 150	-84, 24	32, 150	-84, 24

Hospitalization Status: Inpatient		PLCB-to-FLEX DOSE (N = 127)		40MG-to-FLEX DOSE (N = 188)		80MG-to-FLEX DOSE (N = 189)		Active-to-FLEX DOSE (N = 377)		Overall-to-FLEX DOSE (N = 504)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 8	n	113	113	131	131	150	150	281	281	394	394
	Mean (SD)	71.3 (21.21)	-12.8 (18.50)	75.1 (20.14)	-25.2 (18.25)	75.2 (20.26)	-26.2 (20.24)	75.2 (20.17)	-25.7 (19.31)	74.1 (20.52)	-22.0 (19.93)
	Median	69.0	-11.0	71.0	-25.0	77.5	-22.0	74.0	-24.0	72.0	-20.0
	Min, Max	34, 133	-66, 53	34, 161	-77, 15	30, 130	-86, 15	30, 161	-86, 15	30, 161	-86, 53
On-treatment Week 10	n			128	128	142	142	270	270	270	270
	Mean (SD)			73.2 (20.40)	-27.2 (19.24)	72.9 (20.39)	-28.5 (20.74)	73.0 (20.36)	-27.9 (20.01)	73.0 (20.36)	-27.9 (20.01)
	Median			69.0	-26.5	73.0	-25.0	71.0	-26.0	71.0	-26.0
	Min, Max			32, 167	-94, 21	30, 122	-92, 18	30, 167	-94, 21	30, 167	-94, 21
On-treatment Week 12	n	100	100							100	100
	Mean (SD)	68.1 (20.06)	-15.4 (18.42)							68.1 (20.06)	-15.4 (18.42)
	Median	66.0	-10.5							66.0	-10.5
	Min, Max	32, 137	-66, 33							32, 137	-66, 33
On-treatment Week 14	n			121	121	138	138	259	259	259	259
	Mean (SD)			70.4 (21.02)	-29.6 (21.33)	71.2 (19.95)	-29.8 (19.91)	70.8 (20.42)	-29.7 (20.55)	70.8 (20.42)	-29.7 (20.55)
	Median			67.0	-30.0	71.0	-28.0	70.0	-29.0	70.0	-29.0
	Min, Max			30, 158	-107, 32	30, 121	-87, 10	30, 158	-107, 32	30, 158	-107, 32

Hospitalization Status: Inpatient		PLCB-to-FLEX DOSE (N = 127)		40MG-to-FLEX DOSE (N = 188)		80MG-to-FLEX DOSE (N = 189)		Active-to-FLEX DOSE (N = 377)		Overall-to-FLEX DOSE (N = 504)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 16	n	95	95							95	95
	Mean (SD)	65.4 (18.24)	-17.7 (18.23)							65.4 (18.24)	-17.7 (18.23)
	Median	63.0	-16.0							63.0	-16.0
	Min, Max	31, 122	-64, 23							31, 122	-64, 23
On-treatment Week 18	n			103	103	122	122	225	225	225	225
	Mean (SD)			64.6 (17.29)	-34.9 (18.94)	67.8 (19.07)	-32.9 (20.25)	66.3 (18.31)	-33.8 (19.64)	66.3 (18.31)	-33.8 (19.64)
	Median			63.0	-35.0	67.0	-31.0	66.0	-33.0	66.0	-33.0
	Min, Max			30, 106	-99, 7	30, 111	-95, 11	30, 111	-99, 11	30, 111	-99, 11
On-treatment Week 20	n	86	86							86	86
	Mean (SD)	64.4 (19.83)	-18.9 (20.75)							64.4 (19.83)	-18.9 (20.75)
	Median	63.0	-19.0							63.0	-19.0
	Min, Max	32, 130	-71, 47							32, 130	-71, 47
On-treatment Week 22	n			101	101	118	118	219	219	219	219
	Mean (SD)			62.6 (16.81)	-36.3 (18.92)	66.5 (19.31)	-34.3 (20.21)	64.7 (18.26)	-35.2 (19.61)	64.7 (18.26)	-35.2 (19.61)
	Median			60.0	-37.0	65.0	-32.0	65.0	-34.0	65.0	-34.0
	Min, Max			30, 105	-93, 14	33, 110	-95, 3	30, 110	-95, 14	30, 110	-95, 14
On-treatment Week 24	n	85	85							85	85

Hospitalization Status: Inpatient		PLCB-to-FLEX DOSE (N = 127)		40MG-to-FLEX DOSE (N = 188)		80MG-to-FLEX DOSE (N = 189)		Active-to-FLEX DOSE (N = 377)		Overall-to-FLEX DOSE (N = 504)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	62.5 (19.95)	-21.2 (19.94)							62.5 (19.95)	-21.2 (19.94)
	Median	60.0	-18.0							60.0	-18.0
	Min, Max	31, 130	-69, 32							31, 130	-69, 32
On-treatment Week 26	n			93	93	113	113	206	206	206	206
	Mean (SD)			60.4 (17.67)	-39.4 (18.91)	65.0 (20.98)	-36.0 (21.35)	62.9 (19.64)	-37.5 (20.30)	62.9 (19.64)	-37.5 (20.30)
	Median			58.0	-41.0	64.0	-34.0	60.0	-37.0	60.0	-37.0
	Min, Max			30, 107	-99, 6	32, 118	-97, 20	30, 118	-99, 20	30, 118	-99, 20
On-treatment Week 28	n	79	79							79	79
	Mean (SD)	61.1 (20.04)	-23.5 (19.99)							61.1 (20.04)	-23.5 (19.99)
	Median	59.0	-21.0							59.0	-21.0
	Min, Max	34, 130	-73, 20							34, 130	-73, 20
On-treatment Week 30	n			88	88	109	109	197	197	197	197
	Mean (SD)			58.5 (17.02)	-40.3 (19.16)	63.7 (21.08)	-37.3 (22.05)	61.4 (19.50)	-38.6 (20.81)	61.4 (19.50)	-38.6 (20.81)
	Median			58.0	-42.0	64.0	-36.0	60.0	-38.0	60.0	-38.0
	Min, Max			30, 108	-103, 6	30, 125	-98, 34	30, 125	-103, 34	30, 125	-103, 34
On-treatment Week 34	n			86	86	110	110	196	196	196	196
	Mean (SD)			57.8 (17.03)	-41.0 (19.52)	60.9 (20.20)	-40.0 (20.59)	59.5 (18.89)	-40.4 (20.08)	59.5 (18.89)	-40.4 (20.08)
	Median			58.0	-41.0	60.0	-39.0	59.0	-40.0	59.0	-40.0

Hospitalization Status: Inpatient		PLCB-to-FLEX DOSE (N = 127)		40MG-to-FLEX DOSE (N = 188)		80MG-to-FLEX DOSE (N = 189)		Active-to-FLEX DOSE (N = 377)		Overall-to-FLEX DOSE (N = 504)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			30, 112	-96, 10	30, 117	-108, 10	30, 117	-108, 10	30, 117	-108, 10
On-treatment Week 36	n	14	14							14	14
	Mean (SD)	81.0 (25.66)	-10.1 (19.50)							81.0 (25.66)	-10.1 (19.50)
	Median	85.5	-7.5							85.5	-7.5
	Min, Max	36, 133	-52, 23							36, 133	-52, 23
On-treatment Week 42	n			16	16	25	25	41	41	41	41
	Mean (SD)			73.5 (19.52)	-30.4 (26.81)	81.7 (18.00)	-23.2 (15.95)	78.5 (18.80)	-26.0 (20.85)	78.5 (18.80)	-26.0 (20.85)
	Median			69.5	-26.0	76.0	-24.0	75.0	-25.0	75.0	-25.0
	Min, Max			34, 112	-94, 10	48, 111	-48, 2	34, 112	-94, 10	34, 112	-94, 10
On-treatment Week 44	n	12	12							12	12
	Mean (SD)	75.0 (20.50)	-13.8 (17.95)							75.0 (20.50)	-13.8 (17.95)
	Median	79.5	-10.5							79.5	-10.5
	Min, Max	35, 100	-53, 8							35, 100	-53, 8
On-treatment Week 50	n			16	16	23	23	39	39	39	39
	Mean (SD)			74.6 (21.41)	-29.3 (28.40)	82.4 (19.57)	-21.9 (16.56)	79.2 (20.44)	-24.9 (22.15)	79.2 (20.44)	-24.9 (22.15)
	Median			71.0	-26.0	80.0	-19.0	75.0	-23.0	75.0	-23.0
	Min, Max			35, 120	-90, 18	51, 121	-58, 4	35, 121	-90, 18	35, 121	-90, 18

Hospitalization Status: Inpatient		PLCB-to-FLEX DOSE (N = 127)		40MG-to-FLEX DOSE (N = 188)		80MG-to-FLEX DOSE (N = 189)		Active-to-FLEX DOSE (N = 377)		Overall-to-FLEX DOSE (N = 504)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 52	n	10	10							10	10
	Mean (SD)	74.5 (23.33)	-14.4 (21.08)							74.5 (23.33)	-14.4 (21.08)
	Median	81.0	-6.0							81.0	-6.0
	Min, Max	35, 103	-53, 11							35, 103	-53, 11
On-treatment Week 58	n			13	13	20	20	33	33	33	33
	Mean (SD)			67.7 (20.75)	-37.4 (30.55)	79.7 (18.11)	-24.5 (15.58)	75.0 (19.79)	-29.5 (23.14)	75.0 (19.79)	-29.5 (23.14)
	Median			68.0	-31.0	75.0	-25.0	74.0	-27.0	74.0	-27.0
	Min, Max			33, 105	-102, 9	55, 114	-53, 1	33, 114	-102, 9	33, 114	-102, 9
On-treatment (LOCF)	n	126	126	188	188	187	187	375	375	501	501
	Mean (SD)	69.4 (25.30)	-14.5 (23.93)	78.3 (28.96)	-23.2 (26.62)	72.8 (25.84)	-28.6 (25.45)	75.5 (27.55)	-25.9 (26.15)	74.0 (27.11)	-23.1 (26.06)
	Median	65.0	-12.5	74.5	-22.5	70.0	-30.0	72.0	-25.0	69.0	-22.0
	Min, Max	31, 137	-73, 53	30, 167	-102, 42	30, 136	-108, 34	30, 167	-108, 42	30, 167	-108, 53

Hospitalization Status: Outpatient		PLCB-to-FLEX DOSE (N = 4)		40MG-to-FLEX DOSE (N = 8)		80MG-to-FLEX DOSE (N = 5)		Active-to-FLEX DOSE (N = 13)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	4		8		5		13		17	
	Mean (SD)	97.8 (12.04)		106.0 (8.54)		103.6 (26.88)		105.1 (16.87)		103.4 (15.84)	
	Median	98.5		104.5		93.0		103.0		103.0	
	Min, Max	85, 109		94, 124		82, 149		82, 149		82, 149	

Hospitalization Status: Outpatient		PLCB-to-FLEX DOSE (N = 4)		40MG-to-FLEX DOSE (N = 8)		80MG-to-FLEX DOSE (N = 5)		Active-to-FLEX DOSE (N = 13)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 1	n	4	4	8	8	5	5	13	13	17	17
	Mean (SD)	88.5 (11.12)	-9.3 (16.09)	100.3 (10.35)	-5.8 (6.11)	90.8 (15.93)	-12.8 (39.22)	96.6 (13.04)	-8.5 (23.39)	94.7 (12.78)	-8.6 (21.43)
	Median	88.0	-3.0	100.0	-6.5	87.0	-3.0	98.0	-5.0	97.0	-5.0
	Min, Max	76, 102	-33, 2	80, 116	-14, 5	78, 118	-71, 36	78, 118	-71, 36	76, 118	-71, 36
On-treatment Week 2	n	4	4	7	7	4	4	11	11	15	15
	Mean (SD)	87.3 (12.04)	-10.5 (15.00)	89.9 (16.51)	-16.6 (12.00)	72.0 (19.41)	-37.0 (46.85)	83.4 (18.91)	-24.0 (29.17)	84.4 (17.02)	-20.4 (26.35)
	Median	84.5	-3.0	91.0	-17.0	78.0	-19.0	86.0	-17.0	86.0	-12.0
	Min, Max	76, 104	-33, -3	64, 112	-38, 0	44, 88	-105, -5	44, 112	-105, 0	44, 112	-105, 0
On-treatment Week 4	n	4	4	7	7	4	4	11	11	15	15
	Mean (SD)	90.0 (17.11)	-7.8 (16.52)	90.3 (14.19)	-16.1 (10.64)	72.0 (21.83)	-37.0 (49.12)	83.6 (18.68)	-23.7 (30.04)	85.3 (17.90)	-19.5 (27.51)
	Median	83.5	-4.0	93.0	-18.0	75.5	-24.0	90.0	-18.0	87.0	-15.0
	Min, Max	78, 115	-31, 8	67, 106	-35, 0	44, 93	-105, 5	44, 106	-105, 5	44, 115	-105, 8
On-treatment Week 6	n			6	6	4	4	10	10	10	10
	Mean (SD)			94.0 (15.02)	-12.5 (16.96)	71.8 (27.86)	-37.3 (55.27)	85.1 (22.72)	-22.4 (36.62)	85.1 (22.72)	-22.4 (36.62)
	Median			99.5	-14.5	76.5	-23.0	90.5	-15.0	90.5	-15.0
	Min, Max			69, 108	-33, 14	34, 100	-115, 12	34, 108	-115, 14	34, 108	-115, 14

Hospitalization Status: Outpatient		PLCB-to-FLEX DOSE (N = 4)		40MG-to-FLEX DOSE (N = 8)		80MG-to-FLEX DOSE (N = 5)		Active-to-FLEX DOSE (N = 13)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 7	n			6	6	4	4	10	10	10	10
	Mean (SD)			92.8 (18.20)	-13.7 (20.73)	67.8 (22.91)	-41.3 (50.59)	82.8 (22.95)	-24.7 (35.98)	82.8 (22.95)	-24.7 (35.98)
	Median			96.0	-18.0	77.0	-22.5	82.0	-18.0	82.0	-18.0
	Min, Max			68, 115	-34, 21	34, 83	-115, -5	34, 115	-115, 21	34, 115	-115, 21
On-treatment Week 8	n	4	4	6	6	4	4	10	10	14	14
	Mean (SD)	89.3 (27.54)	-8.5 (26.64)	92.2 (16.85)	-14.3 (19.56)	64.8 (20.71)	-44.3 (48.10)	81.2 (22.38)	-26.3 (34.96)	83.5 (23.15)	-21.2 (32.86)
	Median	81.0	-6.5	95.5	-18.0	73.0	-24.0	77.5	-18.0	78.5	-15.0
	Min, Max	66, 129	-43, 22	69, 113	-33, 19	34, 79	-115, -14	34, 113	-115, 19	34, 129	-115, 22
On-treatment Week 10	n			6	6	4	4	10	10	10	10
	Mean (SD)			91.5 (12.45)	-15.0 (16.15)	57.8 (18.23)	-51.3 (43.53)	78.0 (22.38)	-29.5 (33.57)	78.0 (22.38)	-29.5 (33.57)
	Median			91.0	-21.5	60.5	-36.5	79.5	-24.0	79.5	-24.0
	Min, Max			78, 106	-30, 12	34, 76	-115, -17	34, 106	-115, 12	34, 106	-115, 12
On-treatment Week 12	n	4	4							4	4
	Mean (SD)	85.3 (24.58)	-12.5 (25.36)							85.3 (24.58)	-12.5 (25.36)
	Median	80.5	-7.0							80.5	-7.0
	Min, Max	61, 119	-48, 12							61, 119	-48, 12
On-treatment Week 14	n			6	6	4	4	10	10	10	10

Hospitalization Status: Outpatient		PLCB-to-FLEX DOSE (N = 4)		40MG-to-FLEX DOSE (N = 8)		80MG-to-FLEX DOSE (N = 5)		Active-to-FLEX DOSE (N = 13)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			90.2 (13.85)	-16.3 (12.56)	56.3 (16.88)	-52.8 (43.29)	76.6 (22.54)	-30.9 (32.65)	76.6 (22.54)	-30.9 (32.65)
	Median			91.0	-15.5	59.5	-37.5	77.5	-20.0	77.5	-20.0
	Min, Max			70, 104	-38, -4	33, 73	-116, -20	33, 104	-116, -4	33, 104	-116, -4
On-treatment Week 16	n	4	4							4	4
	Mean (SD)	82.0 (18.65)	-15.8 (21.79)							82.0 (18.65)	-15.8 (21.79)
	Median	81.0	-6.5							81.0	-6.5
	Min, Max	61, 105	-48, -2							61, 105	-48, -2
On-treatment Week 18	n			6	6	4	4	10	10	10	10
	Mean (SD)			87.8 (12.46)	-18.7 (11.04)	57.8 (16.92)	-51.3 (43.93)	75.8 (20.57)	-31.7 (31.53)	75.8 (20.57)	-31.7 (31.53)
	Median			88.0	-17.0	63.5	-33.5	76.0	-21.5	76.0	-21.5
	Min, Max			70, 103	-38, -6	33, 71	-116, -22	33, 103	-116, -6	33, 103	-116, -6
On-treatment Week 20	n	4	4							4	4
	Mean (SD)	80.0 (28.55)	-17.8 (32.62)							80.0 (28.55)	-17.8 (32.62)
	Median	83.0	-4.5							83.0	-4.5
	Min, Max	43, 111	-66, 4							43, 111	-66, 4
On-treatment Week 22	n			6	6	4	4	10	10	10	10
	Mean (SD)			88.0 (12.79)	-18.5 (11.22)	56.5 (16.94)	-52.5 (44.16)	75.4 (21.24)	-32.1 (32.06)	75.4 (21.24)	-32.1 (32.06)
	Median			89.0	-16.0	61.5	-35.5	75.0	-21.0	75.0	-21.0

Hospitalization Status: Outpatient		PLCB-to-FLEX DOSE (N = 4)		40MG-to-FLEX DOSE (N = 8)		80MG-to-FLEX DOSE (N = 5)		Active-to-FLEX DOSE (N = 13)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			69, 104	-39, -5	32, 71	-117, -22	32, 104	-117, -5	32, 104	-117, -5
On-treatment Week 24	n	4	4							4	4
	Mean (SD)	82.3 (30.26)	-15.5 (34.24)							82.3 (30.26)	-15.5 (34.24)
	Median	85.5	-2.0							85.5	-2.0
	Min, Max	43, 115	-66, 8							43, 115	-66, 8
On-treatment Week 26	n			6	6	4	4	10	10	10	10
	Mean (SD)			89.8 (16.27)	-16.7 (14.79)	55.5 (16.38)	-53.5 (43.49)	76.1 (23.47)	-31.4 (33.37)	76.1 (23.47)	-31.4 (33.37)
	Median			88.5	-19.0	63.0	-35.0	74.0	-25.0	74.0	-25.0
	Min, Max			71, 114	-37, 6	31, 65	-118, -26	31, 114	-118, 6	31, 114	-118, 6
On-treatment Week 28	n	4	4							4	4
	Mean (SD)	82.3 (33.09)	-15.5 (35.75)							82.3 (33.09)	-15.5 (35.75)
	Median	82.5	-5.0							82.5	-5.0
	Min, Max	42, 122	-67, 15							42, 122	-67, 15
On-treatment Week 30	n			4	4	4	4	8	8	8	8
	Mean (SD)			83.8 (15.97)	-22.0 (12.68)	56.8 (17.25)	-52.3 (44.51)	70.3 (21.10)	-37.1 (34.34)	70.3 (21.10)	-37.1 (34.34)
	Median			86.0	-22.0	64.5	-35.0	66.5	-28.0	66.5	-28.0
	Min, Max			65, 98	-37, -7	31, 67	-118, -21	31, 98	-118, -7	31, 98	-118, -7

Hospitalization Status: Outpatient		PLCB-to-FLEX DOSE (N = 4)		40MG-to-FLEX DOSE (N = 8)		80MG-to-FLEX DOSE (N = 5)		Active-to-FLEX DOSE (N = 13)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 34	n			5	5	4	4	9	9	9	9
	Mean (SD)			84.8 (10.43)	-21.4 (9.48)	57.0 (17.72)	-52.0 (44.39)	72.4 (19.67)	-35.0 (32.31)	72.4 (19.67)	-35.0 (32.31)
	Median			82.0	-26.0	63.5	-34.0	72.0	-28.0	72.0	-28.0
	Min, Max			72, 96	-30, -8	31, 70	-118, -22	31, 96	-118, -8	31, 96	-118, -8
On-treatment Week 36	n	3	3							3	3
	Mean (SD)	68.7 (24.44)	-26.0 (35.93)							68.7 (24.44)	-26.0 (35.93)
	Median	74.0	-11.0							74.0	-11.0
	Min, Max	42, 90	-67, 0							42, 90	-67, 0
On-treatment Week 42	n			4	4	2	2	6	6	6	6
	Mean (SD)			85.0 (11.05)	-20.8 (10.24)	45.5 (20.51)	-75.5 (60.10)	71.8 (23.95)	-39.0 (39.81)	71.8 (23.95)	-39.0 (39.81)
	Median			85.5	-22.5	45.5	-75.5	75.5	-29.0	75.5	-29.0
	Min, Max			74, 95	-30, -8	31, 60	-118, -33	31, 95	-118, -8	31, 95	-118, -8
On-treatment Week 44	n	3	3							3	3
	Mean (SD)	67.0 (27.50)	-27.7 (38.94)							67.0 (27.50)	-27.7 (38.94)
	Median	73.0	-12.0							73.0	-12.0
	Min, Max	37, 91	-72, 1							37, 91	-72, 1
On-treatment Week 50	n			4	4	2	2	6	6	6	6

Hospitalization Status: Outpatient		PLCB-to-FLEX DOSE (N = 4)		40MG-to-FLEX DOSE (N = 8)		80MG-to-FLEX DOSE (N = 5)		Active-to-FLEX DOSE (N = 13)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			83.8 (10.78)	-22.0 (9.76)	44.5 (19.09)	-76.5 (58.69)	70.7 (23.53)	-40.2 (39.22)	70.7 (23.53)	-40.2 (39.22)
	Median			84.0	-23.5	44.5	-76.5	74.5	-29.0	74.5	-29.0
	Min, Max			73, 94	-32, -9	31, 58	-118, -35	31, 94	-118, -9	31, 94	-118, -9
On-treatment Week 52	n	3	3							3	3
	Mean (SD)	67.0 (27.84)	-27.7 (39.12)							67.0 (27.84)	-27.7 (39.12)
	Median	72.0	-13.0							72.0	-13.0
	Min, Max	37, 92	-72, 2							37, 92	-72, 2
On-treatment Week 58	n			4	4	2	2	6	6	6	6
	Mean (SD)			83.3 (11.95)	-22.5 (12.56)	44.0 (18.38)	-77.0 (57.98)	70.2 (23.75)	-40.7 (39.49)	70.2 (23.75)	-40.7 (39.49)
	Median			84.5	-24.5	44.0	-77.0	73.5	-33.0	73.5	-33.0
	Min, Max			69, 95	-33, -8	31, 57	-118, -36	31, 95	-118, -8	31, 95	-118, -8
On-treatment (LOCF)	n	4	4	8	8	5	5	13	13	17	17
	Mean (SD)	80.8 (35.68)	-17.0 (38.41)	91.8 (15.12)	-14.3 (15.54)	68.4 (31.61)	-35.2 (55.00)	82.8 (24.62)	-22.3 (35.52)	82.3 (26.35)	-21.1 (35.05)
	Median	82.0	-5.5	93.0	-12.5	66.0	-36.0	82.0	-22.0	82.0	-16.0
	Min, Max	37, 122	-72, 15	69, 114	-33, 6	31, 118	-118, 36	31, 118	-118, 36	31, 122	-118, 36

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline values are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-39　PANSS 合計スコア変化量

（20 試験：ロナセンテープ貼付期　Open 52 週、実施国別）

DSP-5423P Dosed Population

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	27		55		57		112		139	
	Mean (SD)	91.7 (16.34)		102.7 (16.85)		104.5 (15.45)		103.6 (16.11)		101.3 (16.77)	
	Median	90.0		101.0		101.0		101.0		99.0	
	Min, Max	62, 121		80, 157		83, 155		80, 157		62, 157	
On-treatment Week 1	n	27	27	55	55	56	56	111	111	138	138
	Mean (SD)	89.1 (17.69)	-2.6 (8.63)	100.8 (17.75)	-1.9 (7.99)	97.9 (15.98)	-6.6 (12.48)	99.3 (16.86)	-4.3 (10.71)	97.3 (17.44)	-3.9 (10.33)
	Median	92.0	-1.0	98.0	-2.0	96.5	-3.0	98.0	-3.0	97.0	-2.0
	Min, Max	60, 133	-33, 14	74, 152	-31, 22	68, 154	-71, 6	68, 154	-71, 22	60, 154	-71, 22
On-treatment Week 2	n	26	26	48	48	52	52	100	100	126	126
	Mean (SD)	87.0 (15.24)	-5.4 (10.93)	96.7 (19.85)	-5.5 (13.56)	93.7 (17.90)	-11.3 (18.61)	95.2 (18.82)	-8.5 (16.56)	93.5 (18.38)	-7.9 (15.57)
	Median	87.0	-3.0	97.0	-3.5	93.5	-7.0	95.0	-6.0	94.0	-5.0
	Min, Max	60, 116	-34, 13	64, 162	-40, 42	44, 127	-105, 13	44, 162	-105, 42	44, 162	-105, 42
On-treatment Week 4	n	26	26	42	42	48	48	90	90	116	116
	Mean (SD)	87.1 (17.39)	-5.3 (11.24)	90.5 (16.99)	-11.8 (14.46)	88.3 (18.05)	-16.6 (21.70)	89.3 (17.50)	-14.3 (18.72)	88.8 (17.42)	-12.3 (17.69)
	Median	85.5	-3.5	90.0	-9.5	90.0	-11.5	90.0	-11.0	90.0	-8.5
	Min, Max	60, 116	-31, 23	65, 132	-61, 6	44, 125	-105, 17	44, 132	-105, 17	44, 132	-105, 23

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 6	n			38	38	46	46	84	84	84	84
	Mean (SD)			88.9 (16.99)	-12.3 (17.78)	86.6 (21.16)	-19.0 (22.48)	87.6 (19.31)	-16.0 (20.64)	87.6 (19.31)	-16.0 (20.64)
	Median			92.0	-8.5	85.0	-14.0	90.0	-12.0	90.0	-12.0
	Min, Max			58, 116	-67, 14	34, 136	-115, 12	34, 136	-115, 14	34, 136	-115, 14
On-treatment Week 7	n			33	33	42	42	75	75	75	75
	Mean (SD)			87.1 (18.13)	-15.5 (18.75)	85.2 (20.37)	-20.1 (22.49)	86.0 (19.31)	-18.1 (20.92)	86.0 (19.31)	-18.1 (20.92)
	Median			82.0	-15.0	87.0	-13.0	85.0	-14.0	85.0	-14.0
	Min, Max			54, 123	-77, 21	34, 123	-115, 13	34, 123	-115, 21	34, 123	-115, 21
On-treatment Week 8	n	25	25	32	32	40	40	72	72	97	97
	Mean (SD)	86.8 (20.13)	-4.6 (15.89)	87.5 (17.78)	-15.3 (19.00)	83.9 (18.32)	-21.7 (23.11)	85.5 (18.05)	-18.8 (21.47)	85.8 (18.51)	-15.2 (21.06)
	Median	87.0	-3.0	81.0	-15.0	83.0	-14.5	82.5	-14.5	83.0	-13.0
	Min, Max	49, 129	-43, 24	61, 123	-77, 19	34, 112	-115, 13	34, 123	-115, 19	34, 129	-115, 24
On-treatment Week 10	n			32	32	38	38	70	70	70	70
	Mean (SD)			86.6 (17.87)	-16.2 (19.93)	81.2 (18.76)	-24.9 (24.42)	83.7 (18.43)	-20.9 (22.74)	83.7 (18.43)	-20.9 (22.74)
	Median			81.5	-15.5	82.0	-17.5	82.0	-17.0	82.0	-17.0
	Min, Max			57, 123	-94, 12	34, 115	-115, 4	34, 123	-115, 12	34, 123	-115, 12

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 12	n	23	23							23	23
	Mean (SD)	83.4 (22.12)	-6.5 (19.18)							83.4 (22.12)	-6.5 (19.18)
	Median	87.0	-5.0							87.0	-5.0
	Min, Max	45, 119	-48, 33							45, 119	-48, 33
On-treatment Week 14	n			31	31	36	36	67	67	67	67
	Mean (SD)			87.3 (23.43)	-15.3 (24.42)	81.3 (20.02)	-22.9 (22.76)	84.1 (21.71)	-19.4 (23.67)	84.1 (21.71)	-19.4 (23.67)
	Median			83.0	-11.0	81.5	-16.0	82.0	-15.0	82.0	-15.0
	Min, Max			50, 158	-107, 32	33, 112	-116, 3	33, 158	-116, 32	33, 158	-116, 32
On-treatment Week 16	n	20	20							20	20
	Mean (SD)	80.5 (20.63)	-10.1 (17.33)							80.5 (20.63)	-10.1 (17.33)
	Median	83.0	-7.0							83.0	-7.0
	Min, Max	41, 116	-48, 16							41, 116	-48, 16
On-treatment Week 18	n			25	25	32	32	57	57	57	57
	Mean (SD)			79.3 (17.20)	-22.9 (22.96)	82.2 (19.57)	-22.5 (24.03)	80.9 (18.46)	-22.7 (23.36)	80.9 (18.46)	-22.7 (23.36)
	Median			76.0	-17.0	83.0	-16.5	81.0	-17.0	81.0	-17.0
	Min, Max			49, 105	-99, 7	33, 111	-116, 11	33, 111	-116, 11	33, 111	-116, 11
On-treatment Week 20	n	19	19							19	19

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	79.1 (22.22)	-12.6 (20.64)							79.1 (22.22)	-12.6 (20.64)
	Median	86.0	-9.0							86.0	-9.0
	Min, Max	39, 116	-66, 23							39, 116	-66, 23
On-treatment Week 22	n			25	25	31	31	56	56	56	56
	Mean (SD)			79.8 (15.66)	-22.4 (21.89)	82.0 (19.37)	-22.9 (23.51)	81.0 (17.69)	-22.7 (22.59)	81.0 (17.69)	-22.7 (22.59)
	Median			78.0	-18.0	79.0	-17.0	78.5	-17.5	78.5	-17.5
	Min, Max			53, 105	-93, 11	32, 110	-117, 3	32, 110	-117, 11	32, 110	-117, 11
On-treatment Week 24	n	18	18							18	18
	Mean (SD)	79.3 (23.82)	-13.3 (20.98)							79.3 (23.82)	-13.3 (20.98)
	Median	85.5	-8.0							85.5	-8.0
	Min, Max	36, 116	-66, 11							36, 116	-66, 11
On-treatment Week 26	n			22	22	31	31	53	53	53	53
	Mean (SD)			78.0 (19.52)	-25.5 (25.34)	82.5 (21.69)	-22.4 (25.29)	80.6 (20.74)	-23.7 (25.11)	80.6 (20.74)	-23.7 (25.11)
	Median			75.5	-21.0	80.0	-18.0	77.0	-19.0	77.0	-19.0
	Min, Max			37, 114	-99, 6	31, 118	-118, 20	31, 118	-118, 20	31, 118	-118, 20
On-treatment Week 28	n	18	18							18	18
	Mean (SD)	80.4 (25.18)	-12.2 (22.52)							80.4 (25.18)	-12.2 (22.52)
	Median	87.5	-9.0							87.5	-9.0

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	36, 122	-67, 20							36, 122	-67, 20
On-treatment Week 30	n			21	21	30	30	51	51	51	51
	Mean (SD)			74.9 (19.24)	-28.4 (26.06)	81.7 (22.54)	-23.7 (26.70)	78.9 (21.31)	-25.6 (26.28)	78.9 (21.31)	-25.6 (26.28)
	Median			71.0	-25.0	78.5	-22.0	76.0	-24.0	76.0	-24.0
	Min, Max			35, 108	-103, 6	31, 125	-118, 34	31, 125	-118, 34	31, 125	-118, 34
On-treatment Week 34	n			21	21	29	29	50	50	50	50
	Mean (SD)			75.7 (19.05)	-27.5 (25.51)	79.0 (21.19)	-27.0 (24.47)	77.6 (20.18)	-27.2 (24.66)	77.6 (20.18)	-27.2 (24.66)
	Median			72.0	-25.0	76.0	-24.0	75.0	-24.5	75.0	-24.5
	Min, Max			34, 112	-96, 10	31, 117	-118, 10	31, 117	-118, 10	31, 117	-118, 10
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	78.8 (25.16)	-12.9 (22.57)							78.8 (25.16)	-12.9 (22.57)
	Median	85.0	-11.0							85.0	-11.0
	Min, Max	36, 133	-67, 23							36, 133	-67, 23
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			75.8 (18.50)	-28.5 (24.49)	79.0 (20.21)	-27.1 (23.84)	77.6 (19.36)	-27.7 (23.86)	77.6 (19.36)	-27.7 (23.86)
	Median			73.5	-26.0	76.0	-27.0	75.0	-27.0	75.0	-27.0
	Min, Max			34, 112	-94, 10	31, 111	-118, 2	31, 112	-118, 10	31, 112	-118, 10

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	73.4 (21.19)	-16.6 (22.42)							73.4 (21.19)	-16.6 (22.42)
	Median	74.0	-11.0							74.0	-11.0
	Min, Max	35, 100	-72, 8							35, 100	-72, 8
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			76.5 (19.86)	-27.8 (25.71)	79.4 (21.83)	-26.2 (24.97)	78.1 (20.79)	-26.9 (25.02)	78.1 (20.79)	-26.9 (25.02)
	Median			73.0	-25.5	77.0	-21.0	75.0	-24.0	75.0	-24.0
	Min, Max			35, 120	-90, 18	31, 121	-118, 4	31, 121	-118, 18	31, 121	-118, 18
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	72.8 (23.42)	-17.5 (24.94)							72.8 (23.42)	-17.5 (24.94)
	Median	77.0	-10.0							77.0	-10.0
	Min, Max	35, 103	-72, 11							35, 103	-72, 11
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			71.4 (19.90)	-33.9 (27.78)	76.5 (20.57)	-29.2 (24.88)	74.2 (20.18)	-31.3 (25.93)	74.2 (20.18)	-31.3 (25.93)
	Median			73.0	-31.0	74.5	-27.5	74.0	-29.0	74.0	-29.0
	Min, Max			33, 105	-102, 9	31, 114	-118, 1	31, 114	-118, 9	31, 114	-118, 9
On-treatment (LOCF)	n	27	27	55	55	56	56	111	111	138	138

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	86.0 (25.80)	-5.7 (22.47)	92.7 (26.13)	-9.9 (26.29)	87.0 (22.83)	-17.5 (26.04)	89.9 (24.58)	-13.7 (26.32)	89.1 (24.77)	-12.2 (25.73)
	Median	92.0	-2.0	94.0	-5.0	83.5	-13.0	90.0	-9.0	91.0	-5.5
	Min, Max	35, 133	-72, 33	33, 162	-102, 42	31, 136	-118, 34	31, 162	-118, 42	31, 162	-118, 42

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	8		9		10		19		27	
	Mean (SD)	73.8 (16.93)		97.0 (8.38)		94.8 (11.82)		95.8 (10.12)		89.3 (15.93)	
	Median	78.5		97.0		99.5		98.0		92.0	
	Min, Max	44, 92		85, 113		81, 116		81, 116		44, 116	
On-treatment Week 1	n	8	8	9	9	10	10	19	19	27	27
	Mean (SD)	74.8 (17.06)	1.0 (5.63)	93.2 (6.80)	-3.8 (7.61)	90.6 (17.43)	-4.2 (8.97)	91.8 (13.20)	-4.0 (8.12)	86.8 (16.19)	-2.5 (7.72)
	Median	79.0	-0.5	93.0	-6.0	96.0	-4.0	94.0	-4.0	91.0	-3.0
	Min, Max	40, 93	-4, 13	82, 104	-12, 15	60, 115	-21, 14	60, 115	-21, 15	40, 115	-21, 15
On-treatment Week 2	n	8	8	8	8	10	10	18	18	26	26
	Mean (SD)	75.0 (17.53)	1.3 (8.03)	89.1 (11.47)	-8.1 (10.58)	88.4 (19.91)	-6.4 (12.32)	88.7 (16.25)	-7.2 (11.28)	84.5 (17.53)	-4.6 (10.97)
	Median	77.5	4.0	88.0	-8.5	94.5	-6.0	92.0	-7.5	84.5	-6.0
	Min, Max	39, 96	-15, 9	73, 105	-24, 14	63, 124	-19, 23	63, 124	-24, 23	39, 124	-24, 23

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 4	n	7	7	7	7	10	10	17	17	24	24
	Mean (SD)	69.3 (13.23)	-2.9 (13.33)	79.1 (11.14)	-19.3 (7.34)	82.6 (18.20)	-12.2 (7.81)	81.2 (15.36)	-15.1 (8.21)	77.7 (15.50)	-11.5 (11.21)
	Median	67.0	4.0	79.0	-23.0	92.5	-10.0	84.0	-15.0	78.0	-12.5
	Min, Max	48, 88	-27, 10	61, 96	-26, -6	54, 105	-28, -2	54, 105	-28, -2	48, 105	-28, 10
On-treatment Week 6	n			6	6	10	10	16	16	16	16
	Mean (SD)			70.0 (7.04)	-26.0 (7.77)	79.5 (18.68)	-15.3 (9.91)	75.9 (15.76)	-19.3 (10.38)	75.9 (15.76)	-19.3 (10.38)
	Median			70.5	-26.0	89.0	-12.0	75.0	-19.0	75.0	-19.0
	Min, Max			61, 79	-35, -16	50, 99	-32, -2	50, 99	-35, -2	50, 99	-35, -2
On-treatment Week 7	n			6	6	10	10	16	16	16	16
	Mean (SD)			66.3 (7.63)	-29.7 (7.94)	79.3 (15.94)	-15.5 (8.10)	74.4 (14.62)	-20.8 (10.51)	74.4 (14.62)	-20.8 (10.51)
	Median			65.5	-27.0	83.0	-14.5	75.0	-21.0	75.0	-21.0
	Min, Max			55, 76	-42, -22	52, 100	-30, -6	52, 100	-42, -6	52, 100	-42, -6
On-treatment Week 8	n	7	7	6	6	10	10	16	16	23	23
	Mean (SD)	64.7 (15.90)	-7.4 (11.25)	65.8 (3.82)	-30.2 (6.05)	80.4 (9.70)	-14.4 (9.72)	74.9 (10.69)	-20.3 (11.45)	71.8 (13.04)	-16.4 (12.67)
	Median	68.0	-2.0	66.5	-29.0	81.5	-13.5	73.0	-22.5	72.0	-18.0
	Min, Max	38, 88	-26, 5	59, 69	-40, -23	63, 98	-31, 1	59, 98	-40, 1	38, 98	-40, 5
On-treatment Week 10	n			5	5	10	10	15	15	15	15

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			66.6 (14.60)	-29.0 (14.68)	78.8 (11.80)	-16.0 (7.87)	74.7 (13.64)	-20.3 (11.90)	74.7 (13.64)	-20.3 (11.90)
	Median			62.0	-34.0	75.5	-16.5	72.0	-18.0	72.0	-18.0
	Min, Max			51, 89	-38, -3	64, 99	-28, -2	51, 99	-38, -2	51, 99	-38, -2
On-treatment Week 12	n	7	7							7	7
	Mean (SD)	66.1 (14.25)	-6.0 (9.35)							66.1 (14.25)	-6.0 (9.35)
	Median	71.0	-3.0							71.0	-3.0
	Min, Max	40, 80	-24, 2							40, 80	-24, 2
On-treatment Week 14	n			5	5	9	9	14	14	14	14
	Mean (SD)			60.4 (5.41)	-36.4 (2.70)	74.1 (12.79)	-22.2 (8.42)	69.2 (12.50)	-27.3 (9.78)	69.2 (12.50)	-27.3 (9.78)
	Median			61.0	-38.0	72.0	-26.0	68.5	-29.5	68.5	-29.5
	Min, Max			52, 66	-39, -33	53, 90	-31, -10	52, 90	-39, -10	52, 90	-39, -10
On-treatment Week 16	n	7	7							7	7
	Mean (SD)	65.6 (13.13)	-6.6 (14.90)							65.6 (13.13)	-6.6 (14.90)
	Median	64.0	-2.0							64.0	-2.0
	Min, Max	43, 84	-27, 15							43, 84	-27, 15
On-treatment Week 18	n			5	5	9	9	14	14	14	14
	Mean (SD)			66.4 (10.83)	-30.4 (5.68)	71.4 (13.81)	-24.9 (9.33)	69.6 (12.64)	-26.9 (8.43)	69.6 (12.64)	-26.9 (8.43)
	Median			66.0	-32.0	73.0	-29.0	70.0	-30.5	70.0	-30.5

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			49, 76	-36, -21	51, 87	-35, -9	49, 87	-36, -9	49, 87	-36, -9
On-treatment Week 20	n	6	6							6	6
	Mean (SD)	62.3 (11.96)	-7.2 (9.91)							62.3 (11.96)	-7.2 (9.91)
	Median	68.0	-3.5							68.0	-3.5
	Min, Max	44, 72	-21, 3							44, 72	-21, 3
On-treatment Week 22	n			5	5	8	8	13	13	13	13
	Mean (SD)			65.0 (12.41)	-31.8 (6.94)	70.3 (14.59)	-25.4 (9.59)	68.2 (13.51)	-27.8 (8.96)	68.2 (13.51)	-27.8 (8.96)
	Median			69.0	-28.0	74.5	-26.0	71.0	-28.0	71.0	-28.0
	Min, Max			43, 73	-42, -26	45, 85	-39, -10	43, 85	-42, -10	43, 85	-42, -10
On-treatment Week 24	n	7	7							7	7
	Mean (SD)	62.4 (15.88)	-9.7 (12.28)							62.4 (15.88)	-9.7 (12.28)
	Median	68.0	-4.0							68.0	-4.0
	Min, Max	40, 88	-36, -1							40, 88	-36, -1
On-treatment Week 26	n			4	4	8	8	12	12	12	12
	Mean (SD)			61.0 (14.67)	-35.3 (6.70)	68.5 (17.31)	-27.1 (11.12)	66.0 (16.22)	-29.8 (10.34)	66.0 (16.22)	-29.8 (10.34)
	Median			64.0	-33.5	70.0	-29.5	68.0	-30.5	68.0	-30.5
	Min, Max			41, 75	-44, -30	40, 93	-44, -10	40, 93	-44, -10	40, 93	-44, -10

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 28	n	7	7							7	7
	Mean (SD)	60.0 (13.38)	-12.1 (11.89)							60.0 (13.38)	-12.1 (11.89)
	Median	62.0	-6.0							62.0	-6.0
	Min, Max	38, 78	-34, 0							38, 78	-34, 0
On-treatment Week 30	n			4	4	7	7	11	11	11	11
	Mean (SD)			57.3 (12.20)	-39.0 (6.48)	63.7 (14.69)	-29.0 (12.32)	61.4 (13.60)	-32.6 (11.36)	61.4 (13.60)	-32.6 (11.36)
	Median			60.5	-40.5	67.0	-33.0	64.0	-34.0	64.0	-34.0
	Min, Max			40, 68	-45, -30	38, 84	-46, -9	38, 84	-46, -9	38, 84	-46, -9
On-treatment Week 34	n			4	4	7	7	11	11	11	11
	Mean (SD)			59.3 (10.34)	-37.0 (5.35)	63.1 (12.06)	-29.6 (11.41)	61.7 (11.10)	-32.3 (10.04)	61.7 (11.10)	-32.3 (10.04)
	Median			63.0	-37.5	64.0	-35.0	63.0	-35.0	63.0	-35.0
	Min, Max			44, 67	-42, -31	42, 81	-42, -11	42, 81	-42, -11	42, 81	-42, -11
On-treatment (LOCF)	n	8	8	9	9	10	10	19	19	27	27
	Mean (SD)	63.0 (15.01)	-10.8 (11.70)	76.7 (19.37)	-20.3 (19.43)	66.6 (13.58)	-28.2 (10.51)	71.4 (16.90)	-24.5 (15.47)	68.9 (16.54)	-20.4 (15.60)
	Median	65.0	-6.0	73.0	-26.0	65.0	-29.5	67.0	-26.0	67.0	-21.0
	Min, Max	38, 84	-34, 0	44, 103	-42, 14	42, 93	-42, -11	42, 103	-42, 14	38, 103	-42, 14

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	

Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	3		7		7		14		17	
	Mean (SD)	103.3 (41.86)		113.4 (17.58)		98.0 (14.55)		105.7 (17.45)		105.3 (21.62)	
	Median	97.0		119.0		96.0		107.0		99.0	
	Min, Max	65, 148		84, 133		82, 119		82, 133		65, 148	
On-treatment Week 1	n	3	3	7	7	7	7	14	14	17	17
	Mean (SD)	102.0 (39.74)	-1.3 (2.31)	107.3 (19.13)	-6.1 (9.51)	100.4 (13.55)	2.4 (16.75)	103.9 (16.32)	-1.9 (13.82)	103.5 (20.35)	-1.8 (12.49)
	Median	97.0	0.0	104.0	-3.0	95.0	0.0	102.5	-2.5	101.0	-2.0
	Min, Max	65, 144	-4, 0	82, 140	-22, 7	83, 118	-13, 36	82, 140	-22, 36	65, 144	-22, 36
On-treatment Week 2	n	3	3	6	6	6	6	12	12	15	15
	Mean (SD)	97.0 (31.51)	-6.3 (11.02)	96.3 (12.23)	-13.8 (11.20)	91.5 (8.69)	-9.2 (15.00)	93.9 (10.42)	-11.5 (12.85)	94.5 (15.13)	-10.5 (12.32)
	Median	96.0	-1.0	94.0	-14.0	90.5	-9.0	92.5	-9.0	93.0	-9.0
	Min, Max	66, 129	-19, 1	80, 117	-25, -2	83, 107	-35, 8	80, 117	-35, 8	66, 129	-35, 8
On-treatment Week 4	n	3	3	6	6	6	6	12	12	15	15
	Mean (SD)	95.7 (32.53)	-7.7 (9.87)	99.0 (12.84)	-11.2 (15.65)	87.8 (7.08)	-12.8 (13.50)	93.4 (11.48)	-12.0 (13.96)	93.9 (15.99)	-11.1 (13.05)
	Median	94.0	-3.0	95.5	-6.5	85.5	-12.0	91.0	-9.0	92.0	-9.0
	Min, Max	64, 129	-19, -1	83, 118	-32, 8	82, 101	-36, 2	82, 118	-36, 8	64, 129	-36, 8
On-treatment Week 6	n			5	5	5	5	10	10	10	10
	Mean (SD)			92.8 (10.62)	-15.0 (20.90)	83.8 (8.90)	-19.4 (15.99)	88.3 (10.38)	-17.2 (17.70)	88.3 (10.38)	-17.2 (17.70)
	Median			93.0	-10.0	82.0	-22.0	90.0	-16.0	90.0	-16.0

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			80, 109	-38, 10	74, 94	-42, -4	74, 109	-42, 10	74, 109	-42, 10
On-treatment Week 7	n			4	4	4	4	8	8	8	8
	Mean (SD)			83.3 (7.59)	-21.8 (24.24)	86.3 (8.92)	-21.3 (11.70)	84.8 (7.83)	-21.5 (17.62)	84.8 (7.83)	-21.5 (17.62)
	Median			81.0	-19.5	90.0	-25.5	86.0	-25.5	86.0	-25.5
	Min, Max			77, 94	-47, -1	73, 92	-30, -4	73, 94	-47, -1	73, 94	-47, -1
On-treatment Week 8	n	3	3	2	2	4	4	6	6	9	9
	Mean (SD)	95.7 (30.37)	-7.7 (17.47)	74.0 (0.00)	-25.5 (21.92)	82.0 (10.71)	-25.5 (11.90)	79.3 (9.27)	-25.5 (13.46)	84.8 (18.73)	-19.6 (16.40)
	Median	104.0	-3.0	74.0	-25.5	87.0	-30.5	80.0	-30.5	86.0	-27.0
	Min, Max	62, 121	-27, 7	74, 74	-41, -10	66, 88	-33, -8	66, 88	-41, -8	62, 121	-41, 7
On-treatment Week 10	n			2	2	4	4	6	6	6	6
	Mean (SD)			71.5 (13.44)	-28.0 (35.36)	81.5 (12.45)	-26.0 (11.17)	78.2 (12.48)	-26.7 (18.05)	78.2 (12.48)	-26.7 (18.05)
	Median			71.5	-28.0	86.5	-29.0	83.5	-29.0	83.5	-29.0
	Min, Max			62, 81	-53, -3	63, 90	-36, -10	62, 90	-53, -3	62, 90	-53, -3
On-treatment Week 12	n	3	3							3	3
	Mean (SD)	94.0 (32.05)	-9.3 (10.21)							94.0 (32.05)	-9.3 (10.21)
	Median	92.0	-5.0							92.0	-5.0
	Min, Max	63, 127	-21, -2							63, 127	-21, -2

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 14	n			1	1	4	4	5	5	5	5
	Mean (SD)			59.0 (.)	-56.0 (.)	82.5 (12.92)	-25.0 (16.85)	77.8 (15.35)	-31.2 (20.13)	77.8 (15.35)	-31.2 (20.13)
	Median			59.0	-56.0	84.5	-32.0	83.0	-34.0	83.0	-34.0
	Min, Max			59, 59	-56, -56	65, 96	-36, 0	59, 96	-56, 0	59, 96	-56, 0
On-treatment Week 16	n	3	3							3	3
	Mean (SD)	91.3 (29.57)	-12.0 (12.49)							91.3 (29.57)	-12.0 (12.49)
	Median	89.0	-8.0							89.0	-8.0
	Min, Max	63, 122	-26, -2							63, 122	-26, -2
On-treatment Week 18	n			1	1	2	2	3	3	3	3
	Mean (SD)			62.0 (.)	-53.0 (.)	75.5 (13.44)	-32.0 (1.41)	71.0 (12.29)	-39.0 (12.17)	71.0 (12.29)	-39.0 (12.17)
	Median			62.0	-53.0	75.5	-32.0	66.0	-33.0	66.0	-33.0
	Min, Max			62, 62	-53, -53	66, 85	-33, -31	62, 85	-53, -31	62, 85	-53, -31
On-treatment Week 20	n	2	2							2	2
	Mean (SD)	97.0 (46.67)	-9.5 (12.02)							97.0 (46.67)	-9.5 (12.02)
	Median	97.0	-9.5							97.0	-9.5
	Min, Max	64, 130	-18, -1							64, 130	-18, -1
On-treatment Week 22	n			1	1	2	2	3	3	3	3

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			57.0 (.)	-58.0 (.)	75.5 (14.85)	-32.0 (2.83)	69.3 (14.98)	-40.7 (15.14)	69.3 (14.98)	-40.7 (15.14)
	Median			57.0	-58.0	75.5	-32.0	65.0	-34.0	65.0	-34.0
	Min, Max			57, 57	-58, -58	65, 86	-34, -30	57, 86	-58, -30	57, 86	-58, -30
On-treatment Week 24	n	2	2							2	2
	Mean (SD)	97.0 (46.67)	-9.5 (12.02)							97.0 (46.67)	-9.5 (12.02)
	Median	97.0	-9.5							97.0	-9.5
	Min, Max	64, 130	-18, -1							64, 130	-18, -1
On-treatment Week 26	n			1	1	2	2	3	3	3	3
	Mean (SD)			53.0 (.)	-62.0 (.)	73.0 (16.97)	-34.5 (4.95)	66.3 (16.65)	-43.7 (16.26)	66.3 (16.65)	-43.7 (16.26)
	Median			53.0	-62.0	73.0	-34.5	61.0	-38.0	61.0	-38.0
	Min, Max			53, 53	-62, -62	61, 85	-38, -31	53, 85	-62, -31	53, 85	-62, -31
On-treatment Week 28	n	2	2							2	2
	Mean (SD)	96.5 (47.38)	-10.0 (11.31)							96.5 (47.38)	-10.0 (11.31)
	Median	96.5	-10.0							96.5	-10.0
	Min, Max	63, 130	-18, -2							63, 130	-18, -2
On-treatment Week 30	n			1	1	2	2	3	3	3	3
	Mean (SD)			52.0 (.)	-63.0 (.)	75.0 (15.56)	-32.5 (3.54)	67.3 (17.24)	-42.7 (17.79)	67.3 (17.24)	-42.7 (17.79)
	Median			52.0	-63.0	75.0	-32.5	64.0	-35.0	64.0	-35.0

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			52, 52	-63, -63	64, 86	-35, -30	52, 86	-63, -30	52, 86	-63, -30
On-treatment Week 34	n			1	1	2	2	3	3	3	3
	Mean (SD)			53.0 (.)	-62.0 (.)	74.5 (16.26)	-33.0 (4.24)	67.3 (16.92)	-42.7 (17.01)	67.3 (16.92)	-42.7 (17.01)
	Median			53.0	-62.0	74.5	-33.0	63.0	-36.0	63.0	-36.0
	Min, Max			53, 53	-62, -62	63, 86	-36, -30	53, 86	-62, -30	53, 86	-62, -30
On-treatment (LOCF)	n	3	3	7	7	7	7	14	14	17	17
	Mean (SD)	94.0 (33.78)	-9.3 (8.08)	96.3 (28.74)	-17.1 (26.37)	88.3 (16.62)	-9.7 (26.29)	92.3 (22.93)	-13.4 (25.59)	92.6 (23.88)	-12.7 (23.30)
	Median	89.0	-8.0	94.0	-4.0	86.0	-4.0	88.0	-4.0	89.0	-4.0
	Min, Max	63, 130	-18, -2	53, 140	-62, 7	63, 118	-36, 36	53, 140	-62, 36	53, 140	-62, 36

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	43		58		54		112		155	
	Mean (SD)	83.3 (21.23)		103.2 (15.90)		103.6 (17.35)		103.4 (16.54)		97.8 (20.03)	
	Median	84.0		101.0		100.0		101.0		98.0	
	Min, Max	38, 126		80, 147		82, 168		80, 168		38, 168	
On-treatment Week 1	n	42	42	58	58	53	53	111	111	153	153
	Mean (SD)	79.2 (21.28)	-3.9 (6.00)	94.7 (18.25)	-8.6 (9.17)	96.2 (19.66)	-7.5 (9.12)	95.4 (18.86)	-8.1 (9.12)	91.0 (20.79)	-6.9 (8.57)

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	79.0	-2.5	90.5	-7.5	94.0	-7.0	92.0	-7.0	88.0	-6.0
	Min, Max	39, 132	-16, 6	63, 154	-32, 12	59, 168	-39, 20	59, 168	-39, 20	39, 168	-39, 20
On-treatment Week 2	n	43	43	53	53	50	50	103	103	146	146
	Mean (SD)	77.5 (21.81)	-5.8 (9.80)	89.2 (20.82)	-14.0 (14.29)	87.4 (20.13)	-16.3 (13.21)	88.3 (20.41)	-15.1 (13.76)	85.1 (21.33)	-12.4 (13.38)
	Median	76.0	-6.0	89.0	-12.0	87.0	-14.0	87.0	-13.0	85.0	-10.0
	Min, Max	38, 141	-22, 21	54, 157	-47, 19	56, 167	-62, 10	54, 167	-62, 19	38, 167	-62, 21
On-treatment Week 4	n	40	40	48	48	46	46	94	94	134	134
	Mean (SD)	74.7 (19.39)	-8.7 (13.53)	82.4 (20.39)	-19.8 (14.84)	79.3 (20.98)	-25.0 (14.07)	80.9 (20.63)	-22.3 (14.63)	79.1 (20.39)	-18.2 (15.57)
	Median	76.0	-9.0	80.0	-18.5	79.0	-23.5	79.0	-20.5	78.0	-18.0
	Min, Max	38, 128	-37, 37	47, 126	-63, 21	43, 146	-51, 7	43, 146	-63, 21	38, 146	-63, 37
On-treatment Week 6	n			44	44	43	43	87	87	87	87
	Mean (SD)			78.1 (19.92)	-23.8 (16.70)	73.9 (20.35)	-29.0 (17.36)	76.0 (20.13)	-26.4 (17.13)	76.0 (20.13)	-26.4 (17.13)
	Median			76.5	-20.0	73.0	-27.0	76.0	-22.0	76.0	-22.0
	Min, Max			41, 118	-73, 6	40, 116	-65, 3	40, 118	-73, 6	40, 118	-73, 6
On-treatment Week 7	n			40	40	41	41	81	81	81	81
	Mean (SD)			75.0 (21.38)	-27.9 (17.80)	73.7 (22.77)	-30.0 (19.94)	74.3 (21.97)	-29.0 (18.83)	74.3 (21.97)	-29.0 (18.83)
	Median			72.5	-26.0	73.0	-29.0	73.0	-28.0	73.0	-28.0
	Min, Max			36, 118	-76, 4	36, 139	-66, 24	36, 139	-76, 24	36, 139	-76, 24

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 8	n	35	35	40	40	41	41	81	81	116	116
	Mean (SD)	71.7 (19.14)	-14.1 (21.45)	72.6 (21.65)	-29.9 (18.99)	72.0 (23.24)	-31.8 (20.83)	72.3 (22.33)	-30.8 (19.84)	72.1 (21.34)	-25.8 (21.66)
	Median	71.0	-13.0	70.5	-29.0	73.0	-34.0	71.0	-32.0	71.0	-24.0
	Min, Max	35, 126	-66, 53	35, 113	-76, 9	39, 130	-70, 15	35, 130	-76, 15	35, 130	-76, 53
On-treatment Week 10	n			40	40	39	39	79	79	79	79
	Mean (SD)			70.1 (19.91)	-32.4 (18.47)	69.7 (23.09)	-33.4 (21.41)	69.9 (21.40)	-32.9 (19.85)	69.9 (21.40)	-32.9 (19.85)
	Median			68.0	-29.0	70.0	-37.0	68.0	-33.0	68.0	-33.0
	Min, Max			33, 111	-79, 2	39, 122	-73, 15	33, 122	-79, 15	33, 122	-79, 15
On-treatment Week 12	n	27	27							27	27
	Mean (SD)	68.3 (19.19)	-18.9 (22.96)							68.3 (19.19)	-18.9 (22.96)
	Median	67.0	-16.0							67.0	-16.0
	Min, Max	32, 137	-66, 12							32, 137	-66, 12
On-treatment Week 14	n			38	38	38	38	76	76	76	76
	Mean (SD)			67.4 (20.09)	-35.8 (19.29)	67.1 (21.30)	-36.5 (22.33)	67.2 (20.57)	-36.2 (20.73)	67.2 (20.57)	-36.2 (20.73)
	Median			64.0	-35.0	64.0	-34.5	64.0	-35.0	64.0	-35.0
	Min, Max			31, 107	-82, 4	36, 121	-86, 10	31, 121	-86, 10	31, 121	-86, 10

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 16	n	26	26							26	26
	Mean (SD)	65.6 (11.34)	-20.1 (21.32)							65.6 (11.34)	-20.1 (21.32)
	Median	64.5	-17.5							64.5	-17.5
	Min, Max	31, 85	-64, 23							31, 85	-64, 23
On-treatment Week 18	n			34	34	30	30	64	64	64	64
	Mean (SD)			62.8 (19.65)	-40.7 (18.69)	59.1 (14.87)	-43.8 (20.88)	61.0 (17.53)	-42.2 (19.65)	61.0 (17.53)	-42.2 (19.65)
	Median			62.0	-39.5	59.5	-44.0	60.0	-40.5	60.0	-40.5
	Min, Max			30, 106	-83, 7	35, 99	-95, -13	30, 106	-95, 7	30, 106	-95, 7
On-treatment Week 20	n	21	21							21	21
	Mean (SD)	62.5 (16.15)	-24.9 (27.33)							62.5 (16.15)	-24.9 (27.33)
	Median	61.0	-25.0							61.0	-25.0
	Min, Max	33, 115	-71, 47							33, 115	-71, 47
On-treatment Week 22	n			33	33	30	30	63	63	63	63
	Mean (SD)			59.8 (17.67)	-43.0 (18.87)	55.4 (14.91)	-47.5 (20.92)	57.7 (16.44)	-45.1 (19.85)	57.7 (16.44)	-45.1 (19.85)
	Median			58.0	-43.0	51.0	-48.5	56.0	-45.0	56.0	-45.0
	Min, Max			32, 102	-84, 14	35, 95	-95, -4	32, 102	-95, 14	32, 102	-95, 14
On-treatment Week 24	n	20	20							20	20

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	59.8 (10.66)	-28.6 (22.58)							59.8 (10.66)	-28.6 (22.58)
	Median	61.5	-31.5							61.5	-31.5
	Min, Max	38, 78	-69, 11							38, 78	-69, 11
On-treatment Week 26	n			30	30	28	28	58	58	58	58
	Mean (SD)			58.5 (17.63)	-45.5 (18.58)	51.9 (15.40)	-51.2 (20.27)	55.3 (16.78)	-48.2 (19.45)	55.3 (16.78)	-48.2 (19.45)
	Median			58.0	-48.0	48.5	-53.5	55.0	-49.5	55.0	-49.5
	Min, Max			32, 102	-83, -1	32, 96	-97, -3	32, 102	-97, -1	32, 102	-97, -1
On-treatment Week 28	n	18	18							18	18
	Mean (SD)	56.3 (10.80)	-34.6 (20.30)							56.3 (10.80)	-34.6 (20.30)
	Median	58.0	-33.0							58.0	-33.0
	Min, Max	37, 70	-70, -1							37, 70	-70, -1
On-treatment Week 30	n			28	28	27	27	55	55	55	55
	Mean (SD)			55.7 (16.54)	-47.6 (17.68)	50.9 (13.05)	-52.6 (19.04)	53.3 (14.98)	-50.1 (18.36)	53.3 (14.98)	-50.1 (18.36)
	Median			54.5	-48.5	47.0	-55.0	52.0	-51.0	52.0	-51.0
	Min, Max			32, 93	-83, -16	34, 83	-98, -19	32, 93	-98, -16	32, 93	-98, -16
On-treatment Week 34	n			28	28	28	28	56	56	56	56
	Mean (SD)			53.6 (15.45)	-49.7 (17.73)	48.4 (12.26)	-54.8 (18.46)	51.0 (14.07)	-52.2 (18.11)	51.0 (14.07)	-52.2 (18.11)
	Median			52.5	-50.5	45.5	-55.0	48.0	-52.5	48.0	-52.5

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			31, 92	-89, -15	32, 77	-108, -18	31, 92	-108, -15	31, 92	-108, -15
On-treatment (LOCF)	n	43	43	58	58	53	53	111	111	154	154
	Mean (SD)	69.9 (22.28)	-13.4 (27.50)	74.2 (28.96)	-29.1 (28.13)	68.3 (28.48)	-35.4 (28.30)	71.4 (28.75)	-32.1 (28.26)	71.0 (27.04)	-26.9 (29.19)
	Median	66.0	-13.0	69.0	-33.0	60.0	-37.0	65.0	-36.0	65.5	-25.0
	Min, Max	37, 137	-70, 53	31, 157	-89, 21	32, 129	-108, 20	31, 157	-108, 21	31, 157	-108, 53

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	22		22		22		44		66	
	Mean (SD)	75.0 (17.51)		99.0 (15.40)		98.9 (13.12)		98.9 (14.14)		90.9 (18.99)	
	Median	73.5		93.5		95.0		94.0		90.0	
	Min, Max	38, 112		83, 138		80, 129		80, 138		38, 138	
On-treatment Week 1	n	22	22	22	22	22	22	44	44	66	66
	Mean (SD)	68.5 (15.84)	-6.4 (9.42)	90.8 (23.30)	-8.2 (17.75)	84.8 (16.27)	-14.1 (18.91)	87.8 (20.09)	-11.1 (18.37)	81.4 (20.77)	-9.6 (16.03)
	Median	69.0	-4.0	89.0	-7.5	86.5	-6.5	87.5	-6.5	83.0	-4.5
	Min, Max	37, 101	-40, 5	45, 139	-41, 36	56, 128	-56, 6	45, 139	-56, 36	37, 139	-56, 36
On-treatment Week 2	n	22	22	21	21	22	22	43	43	65	65
	Mean (SD)	62.6 (13.47)	-12.4 (10.68)	81.0 (18.85)	-16.0 (18.77)	79.8 (20.66)	-19.1 (24.67)	80.4 (19.57)	-17.6 (21.78)	74.4 (19.57)	-15.8 (18.84)

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	63.0	-9.0	83.0	-17.0	84.0	-9.0	83.0	-14.0	74.0	-13.0
	Min, Max	39, 89	-39, 1	36, 125	-50, 37	36, 132	-70, 8	36, 132	-70, 37	36, 132	-70, 37
On-treatment Week 4	n	22	22	21	21	22	22	43	43	65	65
	Mean (SD)	59.2 (13.95)	-15.8 (13.04)	74.7 (18.11)	-22.4 (17.17)	74.3 (21.40)	-24.6 (24.08)	74.5 (19.63)	-23.5 (20.77)	69.3 (19.23)	-20.9 (18.78)
	Median	57.0	-13.5	76.0	-20.0	72.5	-15.5	74.0	-16.0	70.0	-16.0
	Min, Max	43, 83	-48, 8	34, 108	-54, 3	38, 132	-72, 3	34, 132	-72, 3	34, 132	-72, 8
On-treatment Week 6	n			21	21	20	20	41	41	41	41
	Mean (SD)			71.7 (19.66)	-25.4 (18.50)	70.2 (24.03)	-27.9 (27.96)	71.0 (21.64)	-26.6 (23.32)	71.0 (21.64)	-26.6 (23.32)
	Median			75.0	-25.0	69.0	-19.0	72.0	-21.0	72.0	-21.0
	Min, Max			34, 105	-59, 2	36, 132	-80, 7	34, 132	-80, 7	34, 132	-80, 7
On-treatment Week 7	n			21	21	19	19	40	40	40	40
	Mean (SD)			66.7 (15.47)	-30.4 (19.45)	62.8 (22.51)	-33.6 (30.18)	64.9 (18.99)	-31.9 (24.84)	64.9 (18.99)	-31.9 (24.84)
	Median			66.0	-30.0	65.0	-25.0	65.5	-29.0	65.5	-29.0
	Min, Max			32, 94	-74, -4	32, 105	-84, 15	32, 105	-84, 15	32, 105	-84, 15
On-treatment Week 8	n	22	22	21	21	19	19	40	40	62	62
	Mean (SD)	55.8 (21.69)	-19.2 (21.50)	65.2 (15.48)	-31.9 (18.84)	59.2 (21.15)	-37.2 (28.77)	62.4 (18.40)	-34.4 (23.90)	60.0 (19.71)	-29.0 (24.05)
	Median	50.5	-19.5	65.0	-28.0	64.0	-25.0	64.5	-27.5	60.0	-24.5
	Min, Max	34, 133	-50, 47	34, 100	-69, 4	30, 94	-86, 4	30, 100	-86, 4	30, 133	-86, 47

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 10	n			21	21	16	16	37	37	37	37
	Mean (SD)			63.5 (18.04)	-33.6 (21.69)	53.8 (19.96)	-43.4 (28.76)	59.3 (19.25)	-37.8 (25.11)	59.3 (19.25)	-37.8 (25.11)
	Median			64.0	-29.0	47.0	-45.5	63.0	-31.0	63.0	-31.0
	Min, Max			32, 101	-80, 5	30, 87	-85, -3	30, 101	-85, 5	30, 101	-85, 5
On-treatment Week 12	n	20	20							20	20
	Mean (SD)	50.1 (12.11)	-22.5 (13.26)							50.1 (12.11)	-22.5 (13.26)
	Median	46.5	-23.5							46.5	-23.5
	Min, Max	35, 77	-51, -3							35, 77	-51, -3
On-treatment Week 14	n			21	21	17	17	38	38	38	38
	Mean (SD)			59.2 (19.18)	-37.9 (21.79)	55.6 (19.18)	-39.9 (25.89)	57.6 (19.00)	-38.8 (23.40)	57.6 (19.00)	-38.8 (23.40)
	Median			58.0	-33.0	56.0	-38.0	57.5	-35.0	57.5	-35.0
	Min, Max			30, 98	-81, 10	30, 92	-87, 2	30, 98	-87, 10	30, 98	-87, 10
On-treatment Week 16	n	20	20							20	20
	Mean (SD)	47.6 (12.89)	-25.0 (15.45)							47.6 (12.89)	-25.0 (15.45)
	Median	43.5	-27.5							43.5	-27.5
	Min, Max	33, 84	-56, 0							33, 84	-56, 0

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 18	n			18	18	16	16	34	34	34	34
	Mean (SD)			53.8 (15.83)	-42.7 (17.36)	52.5 (18.63)	-44.0 (24.46)	53.2 (16.95)	-43.3 (20.68)	53.2 (16.95)	-43.3 (20.68)
	Median			54.0	-44.5	48.0	-42.5	50.5	-44.5	50.5	-44.5
	Min, Max			30, 88	-81, -17	30, 83	-86, -9	30, 88	-86, -9	30, 88	-86, -9
On-treatment Week 20	n	19	19							19	19
	Mean (SD)	46.3 (11.04)	-26.2 (15.37)							46.3 (11.04)	-26.2 (15.37)
	Median	43.0	-27.0							43.0	-27.0
	Min, Max	32, 75	-56, -1							32, 75	-56, -1
On-treatment Week 22	n			17	17	15	15	32	32	32	32
	Mean (SD)			49.2 (14.30)	-45.2 (15.34)	50.8 (17.49)	-45.3 (22.67)	50.0 (15.63)	-45.2 (18.80)	50.0 (15.63)	-45.2 (18.80)
	Median			50.0	-44.0	44.0	-47.0	46.0	-45.5	46.0	-45.5
	Min, Max			30, 86	-81, -23	33, 80	-88, -10	30, 86	-88, -10	30, 86	-88, -10
On-treatment Week 24	n	19	19							19	19
	Mean (SD)	43.8 (10.67)	-28.6 (15.92)							43.8 (10.67)	-28.6 (15.92)
	Median	42.0	-31.0							42.0	-31.0
	Min, Max	31, 68	-58, -1							31, 68	-58, -1
On-treatment Week 26	n			17	17	14	14	31	31	31	31

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			47.9 (13.40)	-46.5 (13.73)	50.4 (17.76)	-46.4 (23.71)	49.1 (15.30)	-46.4 (18.55)	49.1 (15.30)	-46.4 (18.55)
	Median			44.0	-48.0	41.5	-49.0	43.0	-48.0	43.0	-48.0
	Min, Max			30, 75	-69, -21	33, 82	-88, -8	30, 82	-88, -8	30, 82	-88, -8
On-treatment Week 28	n	16	16							16	16
	Mean (SD)	42.8 (10.53)	-29.4 (17.78)							42.8 (10.53)	-29.4 (17.78)
	Median	39.5	-31.5							39.5	-31.5
	Min, Max	34, 70	-62, -4							34, 70	-62, -4
On-treatment Week 30	n			16	16	14	14	30	30	30	30
	Mean (SD)			46.1 (12.46)	-47.4 (12.21)	49.3 (18.57)	-47.5 (24.56)	47.6 (15.41)	-47.5 (18.65)	47.6 (15.41)	-47.5 (18.65)
	Median			42.5	-49.0	38.5	-51.5	40.5	-49.5	40.5	-49.5
	Min, Max			30, 70	-69, -19	30, 89	-88, -1	30, 89	-88, -1	30, 89	-88, -1
On-treatment Week 34	n			14	14	15	15	29	29	29	29
	Mean (SD)			44.9 (12.40)	-47.0 (12.85)	45.7 (15.84)	-50.3 (21.79)	45.3 (14.03)	-48.7 (17.80)	45.3 (14.03)	-48.7 (17.80)
	Median			41.0	-50.5	37.0	-53.0	38.0	-52.0	38.0	-52.0
	Min, Max			30, 65	-67, -20	30, 79	-90, -11	30, 79	-90, -11	30, 79	-90, -11
On-treatment (LOCF)	n	22	22	22	22	22	22	44	44	66	66
	Mean (SD)	47.4 (21.67)	-27.5 (22.93)	56.5 (26.85)	-42.5 (19.53)	53.0 (25.26)	-45.9 (25.33)	54.7 (25.82)	-44.2 (22.42)	52.3 (24.59)	-38.6 (23.77)
	Median	41.0	-32.0	44.0	-48.5	41.5	-50.0	44.0	-49.0	42.5	-42.0

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	31, 133	-62, 47	30, 139	-67, 10	30, 132	-90, 3	30, 139	-90, 10	30, 139	-90, 47

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	10		13		12		25		35	
	Mean (SD)	85.4 (16.98)		104.7 (20.89)		102.0 (12.63)		103.4 (17.12)		98.3 (18.74)	
	Median	82.0		99.0		104.0		101.0		96.0	
	Min, Max	62, 123		87, 146		85, 129		85, 146		62, 146	
On-treatment Week 1	n	10	10	13	13	12	12	25	25	35	35
	Mean (SD)	85.1 (16.25)	-0.3 (9.62)	103.2 (17.87)	-1.5 (11.52)	94.3 (17.30)	-7.7 (11.25)	98.9 (17.80)	-4.5 (11.58)	95.0 (18.27)	-3.3 (11.08)
	Median	83.5	-0.5	98.0	-1.0	95.5	-5.5	96.0	-4.0	95.0	-4.0
	Min, Max	65, 117	-16, 18	86, 135	-20, 29	65, 131	-37, 6	65, 135	-37, 29	65, 135	-37, 29
On-treatment Week 2	n	10	10	12	12	12	12	24	24	34	34
	Mean (SD)	85.4 (15.81)	0.0 (12.43)	95.6 (18.23)	-9.4 (14.43)	90.7 (16.86)	-11.3 (10.90)	93.1 (17.36)	-10.4 (12.54)	90.9 (17.05)	-7.3 (13.22)
	Median	87.0	-3.5	91.5	-7.0	90.0	-9.5	91.5	-7.0	91.0	-6.5
	Min, Max	67, 108	-16, 21	73, 130	-48, 9	66, 130	-36, 1	66, 130	-48, 9	66, 130	-48, 21
On-treatment Week 4	n	10	10	12	12	12	12	24	24	34	34
	Mean (SD)	85.0 (20.35)	-0.4 (10.56)	91.8 (21.90)	-13.3 (16.10)	88.0 (22.05)	-14.0 (16.73)	89.9 (21.58)	-13.6 (16.06)	88.4 (21.04)	-9.7 (15.74)

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	81.0	2.5	82.0	-12.5	89.5	-11.0	84.0	-11.0	83.0	-8.5
	Min, Max	63, 126	-23, 13	72, 147	-54, 6	47, 138	-55, 9	47, 147	-55, 9	47, 147	-55, 13
On-treatment Week 6	n			12	12	12	12	24	24	24	24
	Mean (SD)			88.7 (22.78)	-16.3 (15.73)	87.5 (22.26)	-14.5 (19.15)	88.1 (22.04)	-15.4 (17.16)	88.1 (22.04)	-15.4 (17.16)
	Median			85.0	-13.5	83.0	-13.0	83.0	-13.5	83.0	-13.5
	Min, Max			59, 146	-50, 2	42, 135	-60, 6	42, 146	-60, 6	42, 146	-60, 6
On-treatment Week 7	n			12	12	11	11	23	23	23	23
	Mean (SD)			89.3 (24.40)	-15.7 (13.60)	87.7 (20.56)	-15.8 (18.85)	88.6 (22.15)	-15.7 (15.94)	88.6 (22.15)	-15.7 (15.94)
	Median			83.5	-16.0	85.0	-15.0	85.0	-15.0	85.0	-15.0
	Min, Max			57, 150	-40, 4	45, 128	-57, 6	45, 150	-57, 6	45, 150	-57, 6
On-treatment Week 8	n	8	8	11	11	11	11	22	22	30	30
	Mean (SD)	71.3 (14.83)	-8.6 (9.44)	89.6 (27.56)	-16.5 (18.13)	83.1 (20.10)	-20.5 (19.47)	86.4 (23.78)	-18.5 (18.47)	82.3 (22.55)	-15.9 (16.98)
	Median	65.5	-8.5	91.0	-21.0	83.0	-20.0	83.5	-20.0	81.5	-12.5
	Min, Max	53, 95	-26, 7	62, 161	-41, 15	42, 118	-60, 8	42, 161	-60, 15	42, 161	-60, 15
On-treatment Week 10	n			11	11	11	11	22	22	22	22
	Mean (SD)			88.4 (29.35)	-18.3 (17.72)	82.8 (18.44)	-20.7 (19.08)	85.6 (24.09)	-19.5 (18.01)	85.6 (24.09)	-19.5 (18.01)
	Median			81.0	-20.0	84.0	-18.0	82.5	-19.0	82.5	-19.0
	Min, Max			57, 167	-43, 21	46, 114	-56, 18	46, 167	-56, 21	46, 167	-56, 21

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 12	n	8	8							8	8
	Mean (SD)	74.3 (9.54)	-5.6 (6.70)							74.3 (9.54)	-5.6 (6.70)
	Median	73.5	-6.5							73.5	-6.5
	Min, Max	64, 86	-15, 6							64, 86	-15, 6
On-treatment Week 14	n			8	8	10	10	18	18	18	18
	Mean (SD)			79.1 (10.16)	-19.1 (13.62)	78.0 (17.00)	-26.3 (16.08)	78.5 (13.99)	-23.1 (15.06)	78.5 (13.99)	-23.1 (15.06)
	Median			80.0	-19.0	74.5	-24.0	78.5	-20.5	78.5	-20.5
	Min, Max			59, 94	-45, 1	42, 104	-60, -8	42, 104	-60, 1	42, 104	-60, 1
On-treatment Week 16	n	8	8							8	8
	Mean (SD)	75.3 (11.95)	-4.6 (8.52)							75.3 (11.95)	-4.6 (8.52)
	Median	79.0	-6.5							79.0	-6.5
	Min, Max	55, 90	-14, 10							55, 90	-14, 10
On-treatment Week 18	n			6	6	9	9	15	15	15	15
	Mean (SD)			73.2 (10.55)	-20.3 (7.89)	73.1 (19.46)	-31.2 (16.28)	73.1 (16.01)	-26.9 (14.29)	73.1 (16.01)	-26.9 (14.29)
	Median			77.0	-18.5	74.0	-31.0	75.0	-22.0	75.0	-22.0
	Min, Max			52, 79	-35, -13	39, 102	-63, -10	39, 102	-63, -10	39, 102	-63, -10

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 20	n	8	8							8	8
	Mean (SD)	76.5 (12.34)	-3.4 (12.94)							76.5 (12.34)	-3.4 (12.94)
	Median	74.0	-4.0							74.0	-4.0
	Min, Max	60, 92	-21, 19							60, 92	-21, 19
On-treatment Week 22	n			6	6	9	9	15	15	15	15
	Mean (SD)			70.3 (12.55)	-23.2 (11.00)	72.8 (16.68)	-31.6 (11.91)	71.8 (14.72)	-28.2 (11.93)	71.8 (14.72)	-28.2 (11.93)
	Median			73.5	-20.5	70.0	-30.0	73.0	-30.0	73.0	-30.0
	Min, Max			47, 82	-40, -10	47, 106	-55, -16	47, 106	-55, -10	47, 106	-55, -10
On-treatment Week 24	n	8	8							8	8
	Mean (SD)	71.4 (12.13)	-8.5 (12.97)							71.4 (12.13)	-8.5 (12.97)
	Median	70.5	-8.0							70.5	-8.0
	Min, Max	50, 87	-31, 15							50, 87	-31, 15
On-treatment Week 26	n			6	6	9	9	15	15	15	15
	Mean (SD)			77.2 (19.10)	-23.0 (9.17)	71.0 (20.30)	-33.3 (14.97)	73.5 (19.38)	-29.2 (13.62)	73.5 (19.38)	-29.2 (13.62)
	Median			78.5	-21.0	74.0	-31.0	76.0	-27.0	76.0	-27.0
	Min, Max			47, 107	-40, -14	38, 108	-64, -11	38, 108	-64, -11	38, 108	-64, -11
On-treatment Week 28	n	8	8							8	8

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	69.3 (14.67)	-10.6 (15.17)							69.3 (14.67)	-10.6 (15.17)
	Median	67.0	-9.5							67.0	-9.5
	Min, Max	50, 93	-35, 14							50, 93	-35, 14
On-treatment Week 30	n			5	5	8	8	13	13	13	13
	Mean (SD)			68.0 (15.86)	-25.8 (12.21)	68.9 (21.02)	-35.1 (15.57)	68.5 (18.49)	-31.5 (14.61)	68.5 (18.49)	-31.5 (14.61)
	Median			74.0	-22.0	68.0	-33.5	72.0	-30.0	72.0	-30.0
	Min, Max			40, 79	-47, -16	36, 110	-66, -17	36, 110	-66, -16	36, 110	-66, -16
On-treatment Week 34	n			5	5	9	9	14	14	14	14
	Mean (SD)			67.4 (12.10)	-26.4 (8.02)	67.6 (21.21)	-36.8 (13.53)	67.5 (17.94)	-33.1 (12.61)	67.5 (17.94)	-33.1 (12.61)
	Median			68.0	-23.0	66.0	-35.0	68.0	-33.0	68.0	-33.0
	Min, Max			49, 83	-38, -18	39, 107	-63, -20	39, 107	-63, -18	39, 107	-63, -18
On-treatment (LOCF)	n	10	10	13	13	12	12	25	25	35	35
	Mean (SD)	78.5 (23.92)	-6.9 (15.69)	92.5 (30.63)	-12.2 (20.86)	73.8 (23.08)	-28.2 (20.79)	83.6 (28.36)	-19.8 (21.96)	82.1 (26.92)	-16.1 (21.00)
	Median	71.0	-5.5	87.0	-18.0	72.5	-30.5	82.0	-22.0	77.0	-20.0
	Min, Max	50, 126	-35, 14	49, 167	-38, 29	39, 114	-63, 18	39, 167	-63, 29	39, 167	-63, 29

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	5		15		17		32		37	
	Mean (SD)	92.8 (27.00)		91.6 (8.42)		93.4 (9.13)		92.6 (8.71)		92.6 (12.10)	
	Median	89.0		91.0		93.0		92.5		92.0	
	Min, Max	63, 134		81, 109		80, 113		80, 113		63, 134	
On-treatment Week 1	n	5	5	15	15	17	17	32	32	37	37
	Mean (SD)	91.8 (26.85)	-1.0 (5.96)	80.9 (12.46)	-10.7 (9.39)	84.2 (13.47)	-9.2 (10.79)	82.7 (12.91)	-9.9 (10.03)	83.9 (15.29)	-8.7 (10.01)
	Median	92.0	-2.0	79.0	-11.0	84.0	-7.0	82.5	-9.0	83.0	-7.0
	Min, Max	61, 127	-7, 7	59, 105	-27, 10	61, 123	-33, 15	59, 123	-33, 15	59, 127	-33, 15
On-treatment Week 2	n	5	5	14	14	16	16	30	30	35	35
	Mean (SD)	88.6 (23.03)	-4.2 (13.29)	70.5 (10.01)	-20.9 (8.92)	73.7 (10.58)	-18.8 (10.55)	72.2 (10.27)	-19.8 (9.71)	74.5 (13.65)	-17.5 (11.48)
	Median	96.0	-5.0	68.5	-19.5	71.0	-16.0	71.0	-17.0	71.0	-17.0
	Min, Max	60, 113	-21, 16	52, 89	-36, -5	56, 100	-35, 1	52, 100	-36, 1	52, 113	-36, 16
On-treatment Week 4	n	5	5	14	14	15	15	29	29	34	34
	Mean (SD)	78.2 (15.71)	-14.6 (23.16)	69.9 (12.23)	-21.5 (12.97)	66.3 (13.16)	-25.7 (15.12)	68.0 (12.62)	-23.7 (14.04)	69.5 (13.36)	-22.4 (15.59)
	Median	79.0	-8.0	66.5	-20.5	66.0	-21.0	66.0	-21.0	68.0	-20.5
	Min, Max	55, 93	-55, 4	49, 92	-44, 0	39, 86	-51, 0	39, 92	-51, 0	39, 93	-55, 4
On-treatment Week 6	n			13	13	15	15	28	28	28	28

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			72.8 (17.37)	-17.2 (13.50)	64.2 (12.27)	-27.9 (15.22)	68.2 (15.21)	-22.9 (15.19)	68.2 (15.21)	-22.9 (15.19)
	Median			64.0	-22.0	66.0	-24.0	65.0	-22.5	65.0	-22.5
	Min, Max			50, 102	-36, 6	38, 85	-52, -6	38, 102	-52, 6	38, 102	-52, 6
On-treatment Week 7	n			10	10	14	14	24	24	24	24
	Mean (SD)			66.5 (13.83)	-23.4 (9.92)	65.7 (13.70)	-27.1 (15.49)	66.0 (13.46)	-25.6 (13.33)	66.0 (13.46)	-25.6 (13.33)
	Median			63.5	-27.0	63.0	-22.5	63.5	-26.0	63.5	-26.0
	Min, Max			53, 94	-33, 0	44, 86	-54, -4	44, 94	-54, 0	44, 94	-54, 0
On-treatment Week 8	n	5	5	9	9	14	14	23	23	28	28
	Mean (SD)	82.8 (20.24)	-10.0 (24.71)	66.0 (14.16)	-23.8 (10.43)	63.6 (12.58)	-29.2 (15.39)	64.6 (12.95)	-27.1 (13.67)	67.8 (15.75)	-24.0 (16.94)
	Median	82.0	-6.0	61.0	-25.0	60.0	-23.5	60.0	-24.0	65.5	-23.5
	Min, Max	56, 113	-52, 12	48, 94	-38, 0	44, 81	-54, -3	44, 94	-54, 0	44, 113	-54, 12
On-treatment Week 10	n			9	9	13	13	22	22	22	22
	Mean (SD)			64.1 (9.60)	-25.7 (7.04)	60.2 (12.01)	-32.2 (15.67)	61.8 (11.02)	-29.5 (13.03)	61.8 (11.02)	-29.5 (13.03)
	Median			64.0	-27.0	59.0	-38.0	60.0	-27.5	60.0	-27.5
	Min, Max			53, 85	-32, -9	41, 81	-53, -9	41, 85	-53, -9	41, 85	-53, -9
On-treatment Week 12	n	4	4							4	4
	Mean (SD)	70.8 (13.02)	-20.0 (30.08)							70.8 (13.02)	-20.0 (30.08)
	Median	73.0	-12.0							73.0	-12.0

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	53, 84	-63, 7							53, 84	-63, 7
On-treatment Week 14	n			9	9	13	13	22	22	22	22
	Mean (SD)			68.8 (15.67)	-21.0 (10.48)	58.4 (13.22)	-33.9 (16.93)	62.6 (14.86)	-28.6 (15.74)	62.6 (14.86)	-28.6 (15.74)
	Median			64.0	-26.0	55.0	-44.0	59.5	-26.0	59.5	-26.0
	Min, Max			53, 96	-30, -1	39, 80	-55, -11	39, 96	-55, -1	39, 96	-55, -1
On-treatment Week 16	n	4	4							4	4
	Mean (SD)	68.3 (10.21)	-22.5 (25.65)							68.3 (10.21)	-22.5 (25.65)
	Median	73.0	-13.5							73.0	-13.5
	Min, Max	53, 74	-60, -3							53, 74	-60, -3
On-treatment Week 18	n			6	6	13	13	19	19	19	19
	Mean (SD)			59.2 (4.07)	-27.2 (7.17)	59.4 (11.53)	-32.9 (15.16)	59.3 (9.66)	-31.1 (13.23)	59.3 (9.66)	-31.1 (13.23)
	Median			58.5	-28.0	63.0	-41.0	61.0	-31.0	61.0	-31.0
	Min, Max			55, 65	-35, -16	43, 77	-50, -8	43, 77	-50, -8	43, 77	-50, -8
On-treatment Week 20	n	4	4							4	4
	Mean (SD)	73.3 (19.74)	-17.5 (35.38)							73.3 (19.74)	-17.5 (35.38)
	Median	71.5	-14.0							71.5	-14.0
	Min, Max	51, 99	-64, 22							51, 99	-64, 22

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 22	n			6	6	13	13	19	19	19	19
	Mean (SD)			61.7 (8.29)	-24.7 (3.93)	60.2 (10.62)	-32.1 (16.19)	60.7 (9.73)	-29.7 (13.84)	60.7 (9.73)	-29.7 (13.84)
	Median			58.5	-24.5	63.0	-31.0	62.0	-26.0	62.0	-26.0
	Min, Max			55, 77	-31, -19	44, 77	-65, -6	44, 77	-65, -6	44, 77	-65, -6
On-treatment Week 24	n	4	4							4	4
	Mean (SD)	77.8 (25.79)	-13.0 (41.96)							77.8 (25.79)	-13.0 (41.96)
	Median	76.0	-7.5							76.0	-7.5
	Min, Max	50, 109	-69, 32							50, 109	-69, 32
On-treatment Week 26	n			5	5	12	12	17	17	17	17
	Mean (SD)			55.2 (6.38)	-29.2 (6.87)	56.9 (10.38)	-36.2 (15.22)	56.4 (9.21)	-34.1 (13.49)	56.4 (9.21)	-34.1 (13.49)
	Median			57.0	-27.0	57.5	-35.0	57.0	-29.0	57.0	-29.0
	Min, Max			45, 62	-41, -23	41, 74	-63, -15	41, 74	-63, -15	41, 74	-63, -15
On-treatment Week 28	n	3	3							3	3
	Mean (SD)	64.3 (16.26)	-31.0 (36.50)							64.3 (16.26)	-31.0 (36.50)
	Median	61.0	-13.0							61.0	-13.0
	Min, Max	50, 82	-73, -7							50, 82	-73, -7
On-treatment Week 30	n			5	5	12	12	17	17	17	17

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			55.0 (8.09)	-29.4 (8.85)	57.2 (14.01)	-35.9 (18.18)	56.5 (12.34)	-34.0 (16.01)	56.5 (12.34)	-34.0 (16.01)
	Median			57.0	-25.0	54.0	-34.5	57.0	-28.0	57.0	-28.0
	Min, Max			41, 61	-45, -24	42, 83	-71, -10	41, 83	-71, -10	41, 83	-71, -10
On-treatment Week 34	n			5	5	11	11	16	16	16	16
	Mean (SD)			53.2 (8.35)	-31.2 (9.18)	55.0 (12.00)	-38.1 (17.42)	54.4 (10.74)	-35.9 (15.35)	54.4 (10.74)	-35.9 (15.35)
	Median			56.0	-28.0	53.0	-36.0	54.5	-30.5	54.5	-30.5
	Min, Max			39, 60	-47, -25	35, 77	-71, -16	35, 77	-71, -16	35, 77	-71, -16
On-treatment (LOCF)	n	5	5	15	15	17	17	32	32	37	37
	Mean (SD)	83.0 (28.06)	-9.8 (39.48)	72.7 (19.96)	-18.9 (17.18)	67.2 (22.13)	-26.2 (22.56)	69.8 (20.99)	-22.8 (20.24)	71.6 (22.09)	-21.0 (23.37)
	Median	82.0	-7.0	65.0	-25.0	64.0	-25.0	64.5	-25.0	65.0	-20.0
	Min, Max	50, 113	-73, 32	39, 105	-47, 10	35, 123	-71, 15	35, 123	-71, 15	35, 123	-73, 32

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	13		17		15		32		45	
	Mean (SD)	89.1 (14.44)		100.4 (6.17)		101.2 (6.25)		100.8 (6.12)		97.4 (10.58)	
	Median	91.0		99.0		102.0		100.5		99.0	
	Min, Max	72, 114		91, 114		88, 114		88, 114		72, 114	

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 1	n	12	12	17	17	15	15	32	32	44	44
	Mean (SD)	82.0 (13.51)	-5.0 (5.05)	93.4 (8.80)	-6.9 (7.11)	94.7 (9.36)	-6.5 (9.36)	94.0 (8.94)	-6.8 (8.11)	90.7 (11.55)	-6.3 (7.38)
	Median	81.5	-4.0	95.0	-3.0	95.0	-4.0	95.0	-4.0	92.5	-4.0
	Min, Max	64, 105	-15, 3	74, 110	-17, 2	78, 112	-25, 5	74, 112	-25, 5	64, 112	-25, 5
On-treatment Week 2	n	12	12	17	17	15	15	32	32	44	44
	Mean (SD)	75.8 (12.00)	-11.3 (8.87)	89.1 (8.42)	-11.2 (7.83)	87.7 (8.39)	-13.5 (8.84)	88.5 (8.30)	-12.3 (8.26)	85.0 (10.92)	-12.0 (8.34)
	Median	74.0	-11.0	89.0	-13.0	89.0	-13.0	89.0	-13.0	86.0	-12.5
	Min, Max	53, 98	-26, 2	72, 103	-28, 3	75, 101	-31, 2	72, 103	-31, 3	53, 103	-31, 3
On-treatment Week 4	n	12	12	17	17	15	15	32	32	44	44
	Mean (SD)	71.0 (11.04)	-16.0 (7.12)	84.7 (12.09)	-15.6 (10.79)	85.3 (10.61)	-15.9 (12.17)	85.0 (11.24)	-15.8 (11.27)	81.2 (12.72)	-15.8 (10.22)
	Median	69.0	-16.0	85.0	-16.0	90.0	-17.0	86.5	-16.5	80.5	-16.5
	Min, Max	49, 92	-28, -6	65, 109	-37, 2	66, 98	-40, 5	65, 109	-40, 5	49, 109	-40, 5
On-treatment Week 6	n			17	17	15	15	32	32	32	32
	Mean (SD)			82.4 (11.44)	-18.0 (10.93)	85.3 (9.57)	-15.9 (13.07)	83.8 (10.54)	-17.0 (11.83)	83.8 (10.54)	-17.0 (11.83)
	Median			85.0	-22.0	87.0	-15.0	85.0	-17.5	85.0	-17.5
	Min, Max			67, 111	-38, 3	64, 100	-39, 12	64, 111	-39, 12	64, 111	-39, 12
On-treatment Week 7	n			16	16	15	15	31	31	31	31

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			75.9 (12.55)	-24.2 (12.21)	82.1 (9.45)	-19.1 (10.97)	78.9 (11.42)	-21.7 (11.71)	78.9 (11.42)	-21.7 (11.71)
	Median			72.5	-26.5	81.0	-16.0	79.0	-24.0	79.0	-24.0
	Min, Max			62, 103	-43, -3	62, 101	-41, -4	62, 103	-43, -3	62, 103	-43, -3
On-treatment Week 8	n	12	12	16	16	15	15	31	31	43	43
	Mean (SD)	65.5 (9.20)	-21.5 (7.87)	74.8 (13.90)	-25.3 (13.60)	78.2 (10.00)	-23.0 (10.80)	76.5 (12.09)	-24.2 (12.17)	73.4 (12.30)	-23.4 (11.11)
	Median	67.0	-21.0	70.0	-30.0	75.0	-21.0	74.0	-28.0	72.0	-25.0
	Min, Max	43, 75	-39, -11	58, 108	-47, 0	64, 99	-39, -5	58, 108	-47, 0	43, 108	-47, 0
On-treatment Week 10	n			14	14	15	15	29	29	29	29
	Mean (SD)			69.8 (11.10)	-30.1 (11.49)	74.1 (11.20)	-27.1 (10.46)	72.0 (11.17)	-28.5 (10.88)	72.0 (11.17)	-28.5 (10.88)
	Median			69.0	-32.5	73.0	-27.0	72.0	-29.0	72.0	-29.0
	Min, Max			53, 93	-49, -6	54, 94	-45, -10	53, 94	-49, -6	53, 94	-49, -6
On-treatment Week 12	n	12	12							12	12
	Mean (SD)	63.6 (8.22)	-23.4 (10.23)							63.6 (8.22)	-23.4 (10.23)
	Median	63.5	-23.0							63.5	-23.0
	Min, Max	44, 76	-47, -9							44, 76	-47, -9
On-treatment Week 14	n			14	14	15	15	29	29	29	29
	Mean (SD)			66.6 (10.54)	-33.3 (9.51)	72.9 (9.86)	-28.3 (10.11)	69.9 (10.52)	-30.7 (9.98)	69.9 (10.52)	-30.7 (9.98)
	Median			69.0	-35.0	71.0	-29.0	70.0	-30.0	70.0	-30.0

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			50, 83	-46, -14	57, 91	-48, -12	50, 91	-48, -12	50, 91	-48, -12
On-treatment Week 16	n	11	11							11	11
	Mean (SD)	60.3 (9.03)	-28.0 (9.94)							60.3 (9.03)	-28.0 (9.94)
	Median	61.0	-26.0							61.0	-26.0
	Min, Max	38, 73	-48, -13							38, 73	-48, -13
On-treatment Week 18	n			14	14	15	15	29	29	29	29
	Mean (SD)			64.8 (9.04)	-35.1 (8.17)	69.3 (9.92)	-31.9 (12.07)	67.1 (9.61)	-33.4 (10.31)	67.1 (9.61)	-33.4 (10.31)
	Median			62.5	-38.0	68.0	-32.0	65.0	-34.0	65.0	-34.0
	Min, Max			50, 80	-46, -18	56, 92	-53, -3	50, 92	-53, -3	50, 92	-53, -3
On-treatment Week 20	n	11	11							11	11
	Mean (SD)	62.8 (11.57)	-25.5 (12.00)							62.8 (11.57)	-25.5 (12.00)
	Median	60.0	-26.0							60.0	-26.0
	Min, Max	38, 80	-49, 0							38, 80	-49, 0
On-treatment Week 22	n			14	14	14	14	28	28	28	28
	Mean (SD)			62.3 (8.57)	-37.6 (7.47)	68.0 (11.07)	-33.6 (11.47)	65.1 (10.14)	-35.6 (9.71)	65.1 (10.14)	-35.6 (9.71)
	Median			62.5	-38.5	65.5	-32.5	63.5	-37.5	63.5	-37.5
	Min, Max			49, 78	-47, -19	54, 97	-54, -12	49, 97	-54, -12	49, 97	-54, -12

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 24	n	11	11							11	11
	Mean (SD)	61.1 (11.60)	-27.2 (11.81)							61.1 (11.60)	-27.2 (11.81)
	Median	59.0	-27.0							59.0	-27.0
	Min, Max	36, 80	-52, -6							36, 80	-52, -6
On-treatment Week 26	n			14	14	13	13	27	27	27	27
	Mean (SD)			59.8 (9.90)	-40.1 (8.18)	63.7 (5.22)	-37.4 (7.62)	61.7 (8.10)	-38.8 (7.88)	61.7 (8.10)	-38.8 (7.88)
	Median			57.0	-41.5	64.0	-36.0	61.0	-40.0	61.0	-40.0
	Min, Max			50, 80	-52, -18	54, 72	-57, -26	50, 80	-57, -18	50, 80	-57, -18
On-treatment Week 28	n	11	11							11	11
	Mean (SD)	59.3 (10.17)	-29.0 (12.19)							59.3 (10.17)	-29.0 (12.19)
	Median	58.0	-30.0							58.0	-30.0
	Min, Max	36, 71	-52, -3							36, 71	-52, -3
On-treatment Week 30	n			12	12	13	13	25	25	25	25
	Mean (SD)			60.3 (8.38)	-37.8 (9.17)	63.2 (7.06)	-37.8 (10.11)	61.8 (7.71)	-37.8 (9.46)	61.8 (7.71)	-37.8 (9.46)
	Median			60.0	-41.0	64.0	-39.0	64.0	-40.0	64.0	-40.0
	Min, Max			51, 77	-50, -20	51, 73	-60, -21	51, 77	-60, -20	51, 77	-60, -20
On-treatment Week 34	n			13	13	13	13	26	26	26	26

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			60.1 (11.67)	-38.7 (12.18)	61.1 (7.05)	-40.0 (9.79)	60.6 (9.46)	-39.3 (10.85)	60.6 (9.46)	-39.3 (10.85)
	Median			57.0	-41.0	63.0	-39.0	58.0	-40.5	58.0	-40.5
	Min, Max			50, 82	-56, -16	50, 71	-62, -22	50, 82	-62, -16	50, 82	-62, -16
On-treatment (LOCF)	n	12	12	17	17	15	15	32	32	44	44
	Mean (SD)	59.5 (9.73)	-27.5 (12.73)	67.2 (17.44)	-33.2 (16.03)	65.5 (13.48)	-35.7 (14.69)	66.4 (15.49)	-34.3 (15.22)	64.5 (14.38)	-32.5 (14.77)
	Median	60.0	-28.5	58.0	-40.0	64.0	-38.0	63.5	-38.5	62.5	-34.5
	Min, Max	36, 71	-52, -3	50, 108	-56, 0	50, 97	-62, -3	50, 108	-62, 0	36, 108	-62, 0

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline values are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

表 2.7.3.6-40　CGI-S スコア変化量

（20 試験：ロナセンテープ貼付期　Open 52 週、実施国別）

DSP-5423P Dosed Population

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	27		55		57		112		139	
	Mean (SD)	3.96 (0.980)		4.64 (0.825)		4.77 (0.887)		4.71 (0.856)		4.56 (0.926)	
	Median	4.00		4.00		5.00		5.00		4.00	
	Min, Max	2, 6		3, 7		3, 7		3, 7		2, 7	

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 1	n	27	27	55	55	56	56	111	111	138	138
	Mean (SD)	3.85 (1.027)	-0.11 (0.424)	4.55 (0.878)	-0.09 (0.554)	4.46 (0.894)	-0.30 (0.761)	4.50 (0.883)	-0.20 (0.672)	4.38 (0.945)	-0.18 (0.631)
	Median	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00
	Min, Max	2, 6	-1, 1	3, 7	-1, 2	3, 7	-3, 2	3, 7	-3, 2	2, 7	-3, 2
On-treatment Week 2	n	26	26	48	48	53	53	101	101	127	127
	Mean (SD)	3.81 (1.096)	-0.15 (0.464)	4.27 (0.893)	-0.29 (0.798)	4.36 (0.942)	-0.43 (1.029)	4.32 (0.916)	-0.37 (0.924)	4.21 (0.973)	-0.32 (0.853)
	Median	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00
	Min, Max	2, 6	-1, 1	3, 7	-2, 3	2, 7	-5, 1	2, 7	-5, 3	2, 7	-5, 3
On-treatment Week 4	n	26	26	42	42	48	48	90	90	116	116
	Mean (SD)	3.81 (1.201)	-0.15 (0.613)	4.00 (0.937)	-0.60 (0.857)	3.96 (1.110)	-0.85 (1.238)	3.98 (1.027)	-0.73 (1.079)	3.94 (1.066)	-0.60 (1.020)
	Median	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00
	Min, Max	2, 6	-1, 1	2, 6	-3, 0	1, 6	-6, 0	1, 6	-6, 0	1, 6	-6, 1
On-treatment Week 6	n			38	38	46	46	84	84	84	84
	Mean (SD)			3.97 (1.000)	-0.61 (0.974)	3.80 (1.088)	-0.98 (1.238)	3.88 (1.046)	-0.81 (1.135)	3.88 (1.046)	-0.81 (1.135)
	Median			4.00	0.00	4.00	-1.00	4.00	0.00	4.00	0.00
	Min, Max			2, 6	-3, 1	1, 6	-6, 0	1, 6	-6, 1	1, 6	-6, 1
On-treatment Week 7	n			33	33	42	42	75	75	75	75

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			3.94 (1.088)	-0.64 (1.025)	3.83 (1.167)	-0.98 (1.297)	3.88 (1.127)	-0.83 (1.190)	3.88 (1.127)	-0.83 (1.190)
	Median			4.00	0.00	4.00	-1.00	4.00	0.00	4.00	0.00
	Min, Max			2, 6	-3, 1	1, 7	-6, 1	1, 7	-6, 1	1, 7	-6, 1
On-treatment Week 8	n	25	25	32	32	40	40	72	72	97	97
	Mean (SD)	3.84 (1.143)	-0.12 (0.726)	3.81 (0.965)	-0.78 (1.070)	3.65 (1.027)	-1.15 (1.272)	3.72 (0.996)	-0.99 (1.193)	3.75 (1.031)	-0.76 (1.153)
	Median	4.00	0.00	4.00	0.00	4.00	-1.00	4.00	-1.00	4.00	0.00
	Min, Max	2, 6	-2, 1	2, 6	-3, 1	1, 6	-6, 0	1, 6	-6, 1	1, 6	-6, 1
On-treatment Week 10	n			32	32	38	38	70	70	70	70
	Mean (SD)			3.75 (0.950)	-0.84 (1.019)	3.55 (0.950)	-1.24 (1.304)	3.64 (0.948)	-1.06 (1.190)	3.64 (0.948)	-1.06 (1.190)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 6	-4, 0	1, 6	-6, 0	1, 6	-6, 0	1, 6	-6, 0
On-treatment Week 12	n	23	23							23	23
	Mean (SD)	3.65 (1.152)	-0.17 (0.834)							3.65 (1.152)	-0.17 (0.834)
	Median	4.00	0.00							4.00	0.00
	Min, Max	1, 6	-2, 1							1, 6	-2, 1
On-treatment Week 14	n			31	31	36	36	67	67	67	67
	Mean (SD)			3.81 (1.250)	-0.77 (1.334)	3.58 (0.906)	-1.17 (1.320)	3.69 (1.076)	-0.99 (1.331)	3.69 (1.076)	-0.99 (1.331)
	Median			4.00	0.00	4.00	-1.00	4.00	-1.00	4.00	-1.00

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			2, 7	-4, 3	1, 6	-6, 0	1, 7	-6, 3	1, 7	-6, 3
On-treatment Week 16	n	20	20							20	20
	Mean (SD)	3.50 (1.192)	-0.35 (0.813)							3.50 (1.192)	-0.35 (0.813)
	Median	4.00	0.00							4.00	0.00
	Min, Max	1, 6	-2, 1							1, 6	-2, 1
On-treatment Week 18	n			25	25	32	32	57	57	57	57
	Mean (SD)			3.48 (0.872)	-1.16 (1.179)	3.63 (0.907)	-1.13 (1.338)	3.56 (0.887)	-1.14 (1.260)	3.56 (0.887)	-1.14 (1.260)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-4, 0	1, 5	-6, 0	1, 5	-6, 0	1, 5	-6, 0
On-treatment Week 20	n	19	19							19	19
	Mean (SD)	3.42 (1.261)	-0.37 (1.165)							3.42 (1.261)	-0.37 (1.165)
	Median	4.00	0.00							4.00	0.00
	Min, Max	1, 6	-3, 3							1, 6	-3, 3
On-treatment Week 22	n			25	25	31	31	56	56	56	56
	Mean (SD)			3.60 (1.000)	-1.04 (1.241)	3.58 (0.923)	-1.13 (1.310)	3.59 (0.949)	-1.09 (1.269)	3.59 (0.949)	-1.09 (1.269)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-3, 1	1, 5	-6, 0	1, 5	-6, 1	1, 5	-6, 1

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 24	n	18	18							18	18
	Mean (SD)	3.39 (1.243)	-0.44 (1.042)							3.39 (1.243)	-0.44 (1.042)
	Median	4.00	0.00							4.00	0.00
	Min, Max	1, 6	-3, 2							1, 6	-3, 2
On-treatment Week 26	n			22	22	31	31	53	53	53	53
	Mean (SD)			3.55 (1.011)	-1.23 (1.478)	3.55 (0.995)	-1.16 (1.393)	3.55 (0.992)	-1.19 (1.415)	3.55 (0.992)	-1.19 (1.415)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-4, 1	1, 6	-6, 1	1, 6	-6, 1	1, 6	-6, 1
On-treatment Week 28	n	18	18							18	18
	Mean (SD)	3.50 (1.339)	-0.33 (1.138)							3.50 (1.339)	-0.33 (1.138)
	Median	4.00	0.00							4.00	0.00
	Min, Max	1, 6	-3, 2							1, 6	-3, 2
On-treatment Week 30	n			21	21	30	30	51	51	51	51
	Mean (SD)			3.38 (1.024)	-1.43 (1.469)	3.47 (0.973)	-1.27 (1.413)	3.43 (0.985)	-1.33 (1.424)	3.43 (0.985)	-1.33 (1.424)
	Median			3.00	-2.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-4, 1	1, 6	-6, 1	1, 6	-6, 1	1, 6	-6, 1
On-treatment Week 34	n			21	21	29	29	50	50	50	50

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			3.33 (1.111)	-1.48 (1.504)	3.34 (0.897)	-1.38 (1.474)	3.34 (0.982)	-1.42 (1.472)	3.34 (0.982)	-1.42 (1.472)
	Median			4.00	-2.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-4, 1	1, 5	-6, 0	1, 5	-6, 1	1, 5	-6, 1
On-treatment Week 36	n	17	17							17	17
	Mean (SD)	3.35 (1.320)	-0.47 (1.007)							3.35 (1.320)	-0.47 (1.007)
	Median	3.00	0.00							3.00	0.00
	Min, Max	1, 6	-3, 1							1, 6	-3, 1
On-treatment Week 42	n			20	20	27	27	47	47	47	47
	Mean (SD)			3.30 (0.979)	-1.55 (1.317)	3.33 (1.000)	-1.41 (1.575)	3.32 (0.980)	-1.47 (1.457)	3.32 (0.980)	-1.47 (1.457)
	Median			4.00	-1.50	3.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-4, 0	1, 6	-6, 2	1, 6	-6, 2	1, 6	-6, 2
On-treatment Week 44	n	15	15							15	15
	Mean (SD)	3.13 (1.125)	-0.53 (1.246)							3.13 (1.125)	-0.53 (1.246)
	Median	3.00	0.00							3.00	0.00
	Min, Max	1, 5	-3, 2							1, 5	-3, 2
On-treatment Week 50	n			20	20	25	25	45	45	45	45
	Mean (SD)			3.45 (0.945)	-1.40 (1.314)	3.32 (0.945)	-1.36 (1.497)	3.38 (0.936)	-1.38 (1.403)	3.38 (0.936)	-1.38 (1.403)
	Median			4.00	-1.50	3.00	-1.00	3.00	-1.00	3.00	-1.00

Country: Japan		PLCB-to-FLEX DOSE (N = 27)		40MG-to-FLEX DOSE (N = 55)		80MG-to-FLEX DOSE (N = 57)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 139)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			2, 5	-4, 1	1, 5	-6, 1	1, 5	-6, 1	1, 5	-6, 1
On-treatment Week 52	n	13	13							13	13
	Mean (SD)	3.08 (1.188)	-0.62 (1.121)							3.08 (1.188)	-0.62 (1.121)
	Median	3.00	0.00							3.00	0.00
	Min, Max	1, 5	-3, 1							1, 5	-3, 1
On-treatment Week 58	n			17	17	22	22	39	39	39	39
	Mean (SD)			3.18 (0.883)	-1.65 (1.320)	3.14 (0.834)	-1.55 (1.471)	3.15 (0.844)	-1.59 (1.390)	3.15 (0.844)	-1.59 (1.390)
	Median			3.00	-2.00	3.00	-1.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-4, 0	1, 4	-6, 0	1, 4	-6, 0	1, 4	-6, 0
On-treatment (LOCF)	n	27	27	55	55	57	57	112	112	139	139
	Mean (SD)	3.74 (1.318)	-0.22 (1.013)	4.20 (1.353)	-0.44 (1.424)	4.02 (1.329)	-0.75 (1.515)	4.11 (1.338)	-0.60 (1.473)	4.04 (1.337)	-0.53 (1.400)
	Median	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00	4.00	0.00
	Min, Max	1, 6	-3, 1	2, 7	-4, 3	1, 7	-6, 2	1, 7	-6, 3	1, 7	-6, 3

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	8		9		10		19		27	
	Mean (SD)	3.38 (1.061)		5.67 (0.707)		5.10 (0.568)		5.37 (0.684)		4.78 (1.219)	

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	3.50		6.00		5.00		5.00		5.00	
	Min, Max	2, 5		4, 6		4, 6		4, 6		2, 6	
On-treatment Week 1	n	8	8	9	9	10	10	19	19	27	27
	Mean (SD)	3.13 (0.835)	-0.25 (0.463)	5.44 (0.882)	-0.22 (0.441)	4.90 (0.738)	-0.20 (0.632)	5.16 (0.834)	-0.21 (0.535)	4.56 (1.251)	-0.22 (0.506)
	Median	3.00	0.00	6.00	0.00	5.00	0.00	5.00	0.00	5.00	0.00
	Min, Max	2, 4	-1, 0	4, 6	-1, 0	4, 6	-1, 1	4, 6	-1, 1	2, 6	-1, 1
On-treatment Week 2	n	8	8	8	8	10	10	18	18	26	26
	Mean (SD)	3.25 (1.035)	-0.13 (0.641)	4.88 (0.991)	-0.75 (0.463)	4.80 (0.919)	-0.30 (1.059)	4.83 (0.924)	-0.50 (0.857)	4.35 (1.198)	-0.38 (0.804)
	Median	3.00	0.00	5.00	-1.00	5.00	0.00	5.00	0.00	5.00	0.00
	Min, Max	2, 5	-1, 1	3, 6	-1, 0	3, 6	-3, 1	3, 6	-3, 1	2, 6	-3, 1
On-treatment Week 4	n	7	7	7	7	10	10	17	17	24	24
	Mean (SD)	2.71 (0.488)	-0.57 (1.272)	4.14 (1.215)	-1.43 (0.976)	4.30 (1.059)	-0.80 (1.135)	4.24 (1.091)	-1.06 (1.088)	3.79 (1.179)	-0.92 (1.139)
	Median	3.00	0.00	4.00	-1.00	4.50	-1.00	4.00	-1.00	3.00	-1.00
	Min, Max	2, 3	-3, 1	3, 6	-3, 0	3, 6	-3, 1	3, 6	-3, 1	2, 6	-3, 1
On-treatment Week 6	n			6	6	10	10	16	16	16	16
	Mean (SD)			3.00 (0.894)	-2.50 (0.548)	3.90 (0.738)	-1.20 (0.919)	3.56 (0.892)	-1.69 (1.014)	3.56 (0.892)	-1.69 (1.014)
	Median			3.00	-2.50	4.00	-1.00	4.00	-2.00	4.00	-2.00
	Min, Max			2, 4	-3, -2	3, 5	-3, 0	2, 5	-3, 0	2, 5	-3, 0

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 7	n			6	6	10	10	16	16	16	16
	Mean (SD)			2.83 (0.753)	-2.67 (1.033)	4.10 (0.738)	-1.00 (0.667)	3.63 (0.957)	-1.63 (1.147)	3.63 (0.957)	-1.63 (1.147)
	Median			3.00	-3.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 4	-4, -1	3, 5	-2, 0	2, 5	-4, 0	2, 5	-4, 0
On-treatment Week 8	n	7	7	6	6	10	10	16	16	23	23
	Mean (SD)	2.57 (0.535)	-0.71 (1.113)	2.50 (0.548)	-3.00 (0.632)	4.10 (0.738)	-1.00 (0.816)	3.50 (1.033)	-1.75 (1.238)	3.22 (0.998)	-1.43 (1.273)
	Median	3.00	0.00	2.50	-3.00	4.00	-1.00	3.50	-2.00	3.00	-1.00
	Min, Max	2, 3	-3, 0	2, 3	-4, -2	3, 5	-2, 0	2, 5	-4, 0	2, 5	-4, 0
On-treatment Week 10	n			5	5	10	10	15	15	15	15
	Mean (SD)			3.00 (1.225)	-2.40 (1.140)	3.90 (0.568)	-1.20 (0.789)	3.60 (0.910)	-1.60 (1.056)	3.60 (0.910)	-1.60 (1.056)
	Median			3.00	-2.00	4.00	-1.00	4.00	-2.00	4.00	-2.00
	Min, Max			2, 5	-4, -1	3, 5	-2, 0	2, 5	-4, 0	2, 5	-4, 0
On-treatment Week 12	n	7	7							7	7
	Mean (SD)	2.71 (0.488)	-0.57 (0.787)							2.71 (0.488)	-0.57 (0.787)
	Median	3.00	0.00							3.00	0.00
	Min, Max	2, 3	-2, 0							2, 3	-2, 0

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 14	n			5	5	9	9	14	14	14	14
	Mean (SD)			2.60 (0.548)	-2.80 (0.837)	3.56 (0.882)	-1.56 (1.236)	3.21 (0.893)	-2.00 (1.240)	3.21 (0.893)	-2.00 (1.240)
	Median			3.00	-3.00	4.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 3	-4, -2	2, 5	-4, 0	2, 5	-4, 0	2, 5	-4, 0
On-treatment Week 16	n	7	7							7	7
	Mean (SD)	3.00 (1.000)	-0.29 (1.604)							3.00 (1.000)	-0.29 (1.604)
	Median	3.00	0.00							3.00	0.00
	Min, Max	2, 5	-3, 2							2, 5	-3, 2
On-treatment Week 18	n			5	5	9	9	14	14	14	14
	Mean (SD)			2.80 (0.447)	-2.60 (1.140)	3.22 (0.833)	-1.89 (1.269)	3.07 (0.730)	-2.14 (1.231)	3.07 (0.730)	-2.14 (1.231)
	Median			3.00	-3.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 3	-4, -1	2, 4	-4, 0	2, 4	-4, 0	2, 4	-4, 0
On-treatment Week 20	n	6	6							6	6
	Mean (SD)	2.83 (0.753)	-0.17 (0.753)							2.83 (0.753)	-0.17 (0.753)
	Median	3.00	0.00							3.00	0.00
	Min, Max	2, 4	-1, 1							2, 4	-1, 1
On-treatment Week 22	n			5	5	8	8	13	13	13	13

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			2.60 (0.894)	-2.80 (0.837)	3.38 (0.744)	-1.63 (1.188)	3.08 (0.862)	-2.08 (1.188)	3.08 (0.862)	-2.08 (1.188)
	Median			2.00	-3.00	3.50	-1.50	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-4, -2	2, 4	-4, 0	2, 4	-4, 0	2, 4	-4, 0
On-treatment Week 24	n	7	7							7	7
	Mean (SD)	2.71 (1.113)	-0.57 (1.272)							2.71 (1.113)	-0.57 (1.272)
	Median	3.00	0.00							3.00	0.00
	Min, Max	1, 4	-3, 1							1, 4	-3, 1
On-treatment Week 26	n			4	4	8	8	12	12	12	12
	Mean (SD)			2.50 (0.577)	-2.75 (0.957)	3.25 (0.707)	-1.75 (1.165)	3.00 (0.739)	-2.08 (1.165)	3.00 (0.739)	-2.08 (1.165)
	Median			2.50	-2.50	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 3	-4, -2	2, 4	-4, 0	2, 4	-4, 0	2, 4	-4, 0
On-treatment Week 28	n	7	7							7	7
	Mean (SD)	2.71 (0.756)	-0.57 (1.134)							2.71 (0.756)	-0.57 (1.134)
	Median	3.00	0.00							3.00	0.00
	Min, Max	2, 4	-3, 0							2, 4	-3, 0
On-treatment Week 30	n			4	4	7	7	11	11	11	11
	Mean (SD)			2.25 (0.500)	-3.00 (0.816)	3.14 (0.690)	-1.86 (1.215)	2.82 (0.751)	-2.27 (1.191)	2.82 (0.751)	-2.27 (1.191)
	Median			2.00	-3.00	3.00	-2.00	3.00	-2.00	3.00	-2.00

Country: China		PLCB-to-FLEX DOSE (N = 8)		40MG-to-FLEX DOSE (N = 9)		80MG-to-FLEX DOSE (N = 10)		Active-to-FLEX DOSE (N = 19)		Overall-to-FLEX DOSE (N = 27)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			2, 3	-4, -2	2, 4	-4, 0	2, 4	-4, 0	2, 4	-4, 0
On-treatment Week 34	n			4	4	7	7	11	11	11	11
	Mean (SD)			2.25 (0.500)	-3.00 (0.816)	3.14 (0.690)	-1.86 (1.215)	2.82 (0.751)	-2.27 (1.191)	2.82 (0.751)	-2.27 (1.191)
	Median			2.00	-3.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 3	-4, -2	2, 4	-4, 0	2, 4	-4, 0	2, 4	-4, 0
On-treatment (LOCF)	n	8	8	9	9	10	10	19	19	27	27
	Mean (SD)	2.88 (0.835)	-0.50 (1.069)	4.00 (1.803)	-1.67 (1.500)	3.30 (0.675)	-1.80 (1.135)	3.63 (1.342)	-1.74 (1.284)	3.41 (1.248)	-1.37 (1.334)
	Median	3.00	0.00	4.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-1.00
	Min, Max	2, 4	-3, 0	2, 6	-4, 0	2, 4	-4, 0	2, 6	-4, 0	2, 6	-4, 0

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	3		7		7		14		17	
	Mean (SD)	4.67 (2.517)		5.43 (1.134)		4.43 (0.787)		4.93 (1.072)		4.88 (1.317)	
	Median	5.00		6.00		4.00		5.00		5.00	
	Min, Max	2, 7		3, 6		4, 6		3, 6		2, 7	
On-treatment Week 1	n	3	3	7	7	7	7	14	14	17	17
	Mean (SD)	4.67 (2.517)	0.00 (0.000)	4.86 (1.069)	-0.57 (0.787)	4.71 (1.113)	0.29 (0.951)	4.79 (1.051)	-0.14 (0.949)	4.76 (1.300)	-0.12 (0.857)

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	5.00	0.00	5.00	0.00	5.00	0.00	5.00	0.00	5.00	0.00
	Min, Max	2, 7	0, 0	3, 6	-2, 0	3, 6	-1, 2	3, 6	-2, 2	2, 7	-2, 2
On-treatment Week 2	n	3	3	6	6	6	6	12	12	15	15
	Mean (SD)	4.33 (2.082)	-0.33 (0.577)	4.17 (0.753)	-1.17 (0.983)	4.00 (0.894)	-0.50 (1.049)	4.08 (0.793)	-0.83 (1.030)	4.13 (1.060)	-0.73 (0.961)
	Median	5.00	0.00	4.00	-1.50	4.00	-0.50	4.00	-1.00	4.00	-1.00
	Min, Max	2, 6	-1, 0	3, 5	-2, 0	3, 5	-2, 1	3, 5	-2, 1	2, 6	-2, 1
On-treatment Week 4	n	3	3	6	6	6	6	12	12	15	15
	Mean (SD)	4.33 (2.082)	-0.33 (0.577)	4.50 (1.049)	-0.83 (1.472)	3.83 (0.753)	-0.67 (0.816)	4.17 (0.937)	-0.75 (1.138)	4.20 (1.146)	-0.67 (1.047)
	Median	5.00	0.00	4.50	-0.50	4.00	-0.50	4.00	-0.50	4.00	0.00
	Min, Max	2, 6	-1, 0	3, 6	-3, 1	3, 5	-2, 0	3, 6	-3, 1	2, 6	-3, 1
On-treatment Week 6	n			5	5	5	5	10	10	10	10
	Mean (SD)			4.40 (1.342)	-0.80 (2.168)	3.80 (0.837)	-0.80 (0.837)	4.10 (1.101)	-0.80 (1.549)	4.10 (1.101)	-0.80 (1.549)
	Median			5.00	0.00	4.00	-1.00	4.00	-0.50	4.00	-0.50
	Min, Max			3, 6	-3, 2	3, 5	-2, 0	3, 6	-3, 2	3, 6	-3, 2
On-treatment Week 7	n			4	4	4	4	8	8	8	8
	Mean (SD)			4.00 (1.155)	-1.00 (2.449)	4.00 (0.816)	-0.75 (0.500)	4.00 (0.926)	-0.88 (1.642)	4.00 (0.926)	-0.88 (1.642)
	Median			4.00	-1.50	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			3, 5	-3, 2	3, 5	-1, 0	3, 5	-3, 2	3, 5	-3, 2

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 8	n	3	3	2	2	4	4	6	6	9	9
	Mean (SD)	4.33 (2.082)	-0.33 (0.577)	3.00 (0.000)	-1.50 (2.121)	4.00 (0.816)	-0.75 (0.500)	3.67 (0.816)	-1.00 (1.095)	3.89 (1.269)	-0.78 (0.972)
	Median	5.00	0.00	3.00	-1.50	4.00	-1.00	3.50	-1.00	4.00	-1.00
	Min, Max	2, 6	-1, 0	3, 3	-3, 0	3, 5	-1, 0	3, 5	-3, 0	2, 6	-3, 0
On-treatment Week 10	n			2	2	4	4	6	6	6	6
	Mean (SD)			3.50 (2.121)	-1.00 (4.243)	4.00 (0.816)	-0.75 (0.500)	3.83 (1.169)	-0.83 (1.941)	3.83 (1.169)	-0.83 (1.941)
	Median			3.50	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 5	-4, 2	3, 5	-1, 0	2, 5	-4, 2	2, 5	-4, 2
On-treatment Week 12	n	3	3							3	3
	Mean (SD)	4.00 (2.000)	-0.67 (0.577)							4.00 (2.000)	-0.67 (0.577)
	Median	4.00	-1.00							4.00	-1.00
	Min, Max	2, 6	-1, 0							2, 6	-1, 0
On-treatment Week 14	n			1	1	4	4	5	5	5	5
	Mean (SD)			2.00 (.)	-4.00 (.)	4.00 (1.155)	-0.75 (1.258)	3.60 (1.342)	-1.40 (1.817)	3.60 (1.342)	-1.40 (1.817)
	Median			2.00	-4.00	4.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			2, 2	-4, -4	3, 5	-2, 1	2, 5	-4, 1	2, 5	-4, 1

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 16	n	3	3							3	3
	Mean (SD)	4.00 (2.000)	-0.67 (0.577)							4.00 (2.000)	-0.67 (0.577)
	Median	4.00	-1.00							4.00	-1.00
	Min, Max	2, 6	-1, 0							2, 6	-1, 0
On-treatment Week 18	n			1	1	2	2	3	3	3	3
	Mean (SD)			2.00 (.)	-4.00 (.)	4.00 (1.414)	-1.00 (0.000)	3.33 (1.528)	-2.00 (1.732)	3.33 (1.528)	-2.00 (1.732)
	Median			2.00	-4.00	4.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			2, 2	-4, -4	3, 5	-1, -1	2, 5	-4, -1	2, 5	-4, -1
On-treatment Week 20	n	2	2							2	2
	Mean (SD)	4.00 (2.828)	-0.50 (0.707)							4.00 (2.828)	-0.50 (0.707)
	Median	4.00	-0.50							4.00	-0.50
	Min, Max	2, 6	-1, 0							2, 6	-1, 0
On-treatment Week 22	n			1	1	2	2	3	3	3	3
	Mean (SD)			2.00 (.)	-4.00 (.)	4.00 (1.414)	-1.00 (0.000)	3.33 (1.528)	-2.00 (1.732)	3.33 (1.528)	-2.00 (1.732)
	Median			2.00	-4.00	4.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			2, 2	-4, -4	3, 5	-1, -1	2, 5	-4, -1	2, 5	-4, -1
On-treatment Week 24	n	2	2							2	2

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	4.00 (2.828)	-0.50 (0.707)							4.00 (2.828)	-0.50 (0.707)
	Median	4.00	-0.50							4.00	-0.50
	Min, Max	2, 6	-1, 0							2, 6	-1, 0
On-treatment Week 26	n			1	1	2	2	3	3	3	3
	Mean (SD)			2.00 (.)	-4.00 (.)	4.00 (1.414)	-1.00 (0.000)	3.33 (1.528)	-2.00 (1.732)	3.33 (1.528)	-2.00 (1.732)
	Median			2.00	-4.00	4.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			2, 2	-4, -4	3, 5	-1, -1	2, 5	-4, -1	2, 5	-4, -1
On-treatment Week 28	n	2	2							2	2
	Mean (SD)	4.00 (2.828)	-0.50 (0.707)							4.00 (2.828)	-0.50 (0.707)
	Median	4.00	-0.50							4.00	-0.50
	Min, Max	2, 6	-1, 0							2, 6	-1, 0
On-treatment Week 30	n			1	1	2	2	3	3	3	3
	Mean (SD)			2.00 (.)	-4.00 (.)	4.00 (1.414)	-1.00 (0.000)	3.33 (1.528)	-2.00 (1.732)	3.33 (1.528)	-2.00 (1.732)
	Median			2.00	-4.00	4.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			2, 2	-4, -4	3, 5	-1, -1	2, 5	-4, -1	2, 5	-4, -1
On-treatment Week 34	n			1	1	2	2	3	3	3	3
	Mean (SD)			2.00 (.)	-4.00 (.)	4.00 (1.414)	-1.00 (0.000)	3.33 (1.528)	-2.00 (1.732)	3.33 (1.528)	-2.00 (1.732)
	Median			2.00	-4.00	4.00	-1.00	3.00	-1.00	3.00	-1.00

Country: Korea		PLCB-to-FLEX DOSE (N = 3)		40MG-to-FLEX DOSE (N = 7)		80MG-to-FLEX DOSE (N = 7)		Active-to-FLEX DOSE (N = 14)		Overall-to-FLEX DOSE (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			2, 2	-4, -4	3, 5	-1, -1	2, 5	-4, -1	2, 5	-4, -1
On-treatment (LOCF)	n	3	3	7	7	7	7	14	14	17	17
	Mean (SD)	4.00 (2.000)	-0.67 (0.577)	4.57 (1.512)	-0.86 (2.035)	4.29 (1.113)	-0.14 (1.345)	4.43 (1.284)	-0.50 (1.698)	4.35 (1.367)	-0.53 (1.546)
	Median	4.00	-1.00	5.00	0.00	4.00	0.00	5.00	0.00	5.00	0.00
	Min, Max	2, 6	-1, 0	2, 6	-4, 2	3, 6	-2, 2	2, 6	-4, 2	2, 6	-4, 2

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	43		58		54		112		155	
	Mean (SD)	4.09 (0.947)		4.91 (0.629)		5.15 (0.529)		5.03 (0.592)		4.77 (0.820)	
	Median	4.00		5.00		5.00		5.00		5.00	
	Min, Max	2, 6		4, 6		4, 6		4, 6		2, 6	
On-treatment Week 1	n	42	42	58	58	53	53	111	111	153	153
	Mean (SD)	3.95 (0.962)	-0.14 (0.417)	4.64 (0.718)	-0.28 (0.523)	4.77 (0.724)	-0.38 (0.596)	4.70 (0.721)	-0.32 (0.559)	4.50 (0.859)	-0.27 (0.529)
	Median	4.00	0.00	5.00	0.00	5.00	0.00	5.00	0.00	5.00	0.00
	Min, Max	1, 6	-1, 1	3, 6	-1, 1	3, 6	-2, 1	3, 6	-2, 1	1, 6	-2, 1
On-treatment Week 2	n	43	43	53	53	50	50	103	103	146	146
	Mean (SD)	3.88 (0.956)	-0.21 (0.600)	4.36 (0.963)	-0.55 (0.952)	4.42 (0.859)	-0.72 (0.784)	4.39 (0.910)	-0.63 (0.874)	4.24 (0.949)	-0.51 (0.824)

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	4.00	0.00	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	0.00
	Min, Max	1, 6	-2, 1	3, 7	-2, 2	3, 6	-2, 1	3, 7	-2, 2	1, 7	-2, 2
On-treatment Week 4	n	40	40	48	48	46	46	94	94	134	134
	Mean (SD)	3.78 (0.832)	-0.30 (0.939)	4.04 (0.922)	-0.83 (0.859)	4.00 (1.054)	-1.13 (0.980)	4.02 (0.984)	-0.98 (0.927)	3.95 (0.944)	-0.78 (0.978)
	Median	4.00	0.00	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	2, 6	-2, 3	2, 6	-3, 1	1, 6	-4, 0	1, 6	-4, 1	1, 6	-4, 3
On-treatment Week 6	n			44	44	43	43	87	87	87	87
	Mean (SD)			3.93 (0.950)	-0.89 (1.083)	3.86 (1.146)	-1.26 (1.049)	3.90 (1.046)	-1.07 (1.076)	3.90 (1.046)	-1.07 (1.076)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			1, 5	-4, 1	1, 6	-4, 1	1, 6	-4, 1	1, 6	-4, 1
On-treatment Week 7	n			40	40	41	41	81	81	81	81
	Mean (SD)			3.80 (0.966)	-1.08 (1.047)	3.85 (1.131)	-1.29 (1.031)	3.83 (1.046)	-1.19 (1.038)	3.83 (1.046)	-1.19 (1.038)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			1, 5	-4, 1	1, 6	-4, 0	1, 6	-4, 1	1, 6	-4, 1
On-treatment Week 8	n	35	35	40	40	41	41	81	81	116	116
	Mean (SD)	3.60 (1.168)	-0.54 (1.358)	3.60 (1.033)	-1.25 (1.127)	3.73 (1.225)	-1.41 (1.095)	3.67 (1.129)	-1.33 (1.107)	3.65 (1.136)	-1.09 (1.237)
	Median	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	1, 6	-4, 4	1, 5	-4, 1	1, 6	-4, 0	1, 6	-4, 1	1, 6	-4, 4

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 10	n			40	40	39	39	79	79	79	79
	Mean (SD)			3.45 (0.986)	-1.40 (1.128)	3.56 (1.188)	-1.59 (1.069)	3.51 (1.085)	-1.49 (1.096)	3.51 (1.085)	-1.49 (1.096)
	Median			3.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			1, 5	-4, 1	2, 6	-4, 0	1, 6	-4, 1	1, 6	-4, 1
On-treatment Week 12	n	27	27							27	27
	Mean (SD)	3.33 (1.038)	-0.89 (1.188)							3.33 (1.038)	-0.89 (1.188)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	1, 5	-4, 1							1, 5	-4, 1
On-treatment Week 14	n			38	38	38	38	76	76	76	76
	Mean (SD)			3.34 (1.072)	-1.53 (1.179)	3.50 (1.225)	-1.63 (1.149)	3.42 (1.146)	-1.58 (1.158)	3.42 (1.146)	-1.58 (1.158)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 1	2, 7	-4, 1	1, 7	-4, 1	1, 7	-4, 1
On-treatment Week 16	n	26	26							26	26
	Mean (SD)	3.46 (0.905)	-0.73 (1.185)							3.46 (0.905)	-0.73 (1.185)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	2, 5	-3, 1							2, 5	-3, 1

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 18	n			34	34	30	30	64	64	64	64
	Mean (SD)			3.06 (1.043)	-1.82 (1.086)	3.07 (0.980)	-1.97 (1.098)	3.06 (1.006)	-1.89 (1.086)	3.06 (1.006)	-1.89 (1.086)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 1	2, 5	-4, 0	1, 5	-4, 1	1, 5	-4, 1
On-treatment Week 20	n	21	21							21	21
	Mean (SD)	3.10 (0.944)	-1.14 (1.108)							3.10 (0.944)	-1.14 (1.108)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	2, 5	-3, 1							2, 5	-3, 1
On-treatment Week 22	n			33	33	30	30	63	63	63	63
	Mean (SD)			2.85 (1.034)	-2.03 (1.132)	2.87 (1.008)	-2.17 (1.117)	2.86 (1.014)	-2.10 (1.118)	2.86 (1.014)	-2.10 (1.118)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 1	1, 5	-4, 0	1, 5	-4, 1	1, 5	-4, 1
On-treatment Week 24	n	20	20							20	20
	Mean (SD)	3.10 (0.968)	-1.15 (1.226)							3.10 (0.968)	-1.15 (1.226)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	2, 5	-3, 2							2, 5	-3, 2
On-treatment Week 26	n			30	30	28	28	58	58	58	58

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			2.67 (1.028)	-2.27 (1.015)	2.68 (1.056)	-2.36 (1.096)	2.67 (1.033)	-2.31 (1.046)	2.67 (1.033)	-2.31 (1.046)
	Median			2.00	-2.00	2.50	-2.50	2.00	-2.00	2.00	-2.00
	Min, Max			1, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0
On-treatment Week 28	n	18	18							18	18
	Mean (SD)	2.78 (0.808)	-1.56 (0.922)							2.78 (0.808)	-1.56 (0.922)
	Median	3.00	-1.50							3.00	-1.50
	Min, Max	2, 4	-3, 0							2, 4	-3, 0
On-treatment Week 30	n			28	28	27	27	55	55	55	55
	Mean (SD)			2.64 (0.911)	-2.21 (0.917)	2.52 (0.849)	-2.52 (0.975)	2.58 (0.875)	-2.36 (0.950)	2.58 (0.875)	-2.36 (0.950)
	Median			2.00	-2.00	2.00	-3.00	2.00	-2.00	2.00	-2.00
	Min, Max			1, 5	-4, 0	1, 4	-4, -1	1, 5	-4, 0	1, 5	-4, 0
On-treatment Week 34	n			28	28	28	28	56	56	56	56
	Mean (SD)			2.61 (0.786)	-2.25 (0.799)	2.39 (0.832)	-2.64 (0.951)	2.50 (0.809)	-2.45 (0.893)	2.50 (0.809)	-2.45 (0.893)
	Median			2.50	-2.00	2.00	-3.00	2.00	-2.50	2.00	-2.50
	Min, Max			1, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1
On-treatment (LOCF)	n	43	43	58	58	53	53	111	111	154	154
	Mean (SD)	3.63 (1.254)	-0.47 (1.486)	3.67 (1.491)	-1.24 (1.490)	3.45 (1.526)	-1.70 (1.381)	3.57 (1.505)	-1.46 (1.451)	3.58 (1.436)	-1.18 (1.523)
	Median	4.00	0.00	3.50	-1.00	3.00	-2.00	3.00	-2.00	3.00	-1.00

Country: Malaysia		PLCB-to-FLEX DOSE (N = 43)		40MG-to-FLEX DOSE (N = 58)		80MG-to-FLEX DOSE (N = 54)		Active-to-FLEX DOSE (N = 112)		Overall-to-FLEX DOSE (N = 155)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	2, 6	-3, 4	1, 7	-4, 1	1, 7	-4, 1	1, 7	-4, 1	1, 7	-4, 4

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	22		22		22		44		66	
	Mean (SD)	4.00 (1.113)		4.82 (0.853)		4.86 (0.640)		4.84 (0.745)		4.56 (0.963)	
	Median	4.00		5.00		5.00		5.00		5.00	
	Min, Max	2, 6		4, 7		4, 6		4, 7		2, 7	
On-treatment Week 1	n	22	22	22	22	22	22	44	44	66	66
	Mean (SD)	3.68 (0.995)	-0.32 (0.646)	4.59 (1.098)	-0.23 (0.612)	4.32 (0.780)	-0.55 (0.800)	4.45 (0.951)	-0.39 (0.722)	4.20 (1.026)	-0.36 (0.694)
	Median	3.50	0.00	5.00	0.00	4.00	0.00	5.00	0.00	4.00	0.00
	Min, Max	2, 6	-2, 1	3, 7	-1, 1	3, 6	-3, 0	3, 7	-3, 1	2, 7	-3, 1
On-treatment Week 2	n	22	22	21	21	22	22	43	43	65	65
	Mean (SD)	3.32 (0.995)	-0.68 (0.945)	4.10 (0.995)	-0.62 (0.590)	4.14 (1.037)	-0.73 (0.935)	4.12 (1.005)	-0.67 (0.778)	3.85 (1.064)	-0.68 (0.831)
	Median	3.00	-0.50	4.00	-1.00	4.00	0.00	4.00	-1.00	4.00	-1.00
	Min, Max	2, 6	-3, 1	2, 6	-2, 0	2, 6	-3, 0	2, 6	-3, 0	2, 6	-3, 1
On-treatment Week 4	n	22	22	21	21	22	22	43	43	65	65
	Mean (SD)	3.23 (0.612)	-0.77 (1.232)	3.81 (1.078)	-0.90 (0.768)	3.91 (1.019)	-0.95 (0.999)	3.86 (1.037)	-0.93 (0.884)	3.65 (0.959)	-0.88 (1.008)

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Median	3.00	-0.50	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	2, 4	-4, 1	2, 6	-2, 0	2, 6	-3, 0	2, 6	-3, 0	2, 6	-4, 1
On-treatment Week 6	n			21	21	20	20	41	41	41	41
	Mean (SD)			3.71 (1.102)	-1.00 (0.775)	3.65 (1.182)	-1.20 (1.056)	3.68 (1.128)	-1.10 (0.917)	3.68 (1.128)	-1.10 (0.917)
	Median			4.00	-1.00	3.50	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 6	-2, 0	1, 6	-3, 0	1, 6	-3, 0	1, 6	-3, 0
On-treatment Week 7	n			21	21	19	19	40	40	40	40
	Mean (SD)			3.38 (0.805)	-1.33 (0.658)	3.32 (1.157)	-1.47 (1.172)	3.35 (0.975)	-1.40 (0.928)	3.35 (0.975)	-1.40 (0.928)
	Median			3.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			2, 5	-2, 0	1, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0
On-treatment Week 8	n	22	22	21	21	19	19	40	40	62	62
	Mean (SD)	2.86 (0.990)	-1.14 (1.167)	3.24 (0.768)	-1.48 (0.750)	3.05 (1.026)	-1.74 (1.098)	3.15 (0.893)	-1.60 (0.928)	3.05 (0.931)	-1.44 (1.034)
	Median	3.00	-1.00	3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-1.00
	Min, Max	1, 6	-4, 1	2, 5	-3, 0	1, 5	-4, 0	1, 5	-4, 0	1, 6	-4, 1
On-treatment Week 10	n			21	21	16	16	37	37	37	37
	Mean (SD)			3.19 (0.814)	-1.52 (0.928)	2.88 (1.088)	-2.00 (1.155)	3.05 (0.941)	-1.73 (1.045)	3.05 (0.941)	-1.73 (1.045)
	Median			3.00	-1.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 12	n	20	20							20	20
	Mean (SD)	2.55 (0.686)	-1.25 (1.020)							2.55 (0.686)	-1.25 (1.020)
	Median	2.00	-1.00							2.00	-1.00
	Min, Max	2, 4	-4, 0							2, 4	-4, 0
On-treatment Week 14	n			21	21	17	17	38	38	38	38
	Mean (SD)			3.05 (1.024)	-1.67 (0.966)	3.06 (1.144)	-1.82 (1.286)	3.05 (1.064)	-1.74 (1.107)	3.05 (1.064)	-1.74 (1.107)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0
On-treatment Week 16	n	20	20							20	20
	Mean (SD)	2.50 (0.607)	-1.30 (1.031)							2.50 (0.607)	-1.30 (1.031)
	Median	2.00	-1.00							2.00	-1.00
	Min, Max	2, 4	-4, 0							2, 4	-4, 0
On-treatment Week 18	n			18	18	16	16	34	34	34	34
	Mean (SD)			2.61 (0.778)	-2.06 (0.938)	2.75 (1.065)	-2.19 (1.109)	2.68 (0.912)	-2.12 (1.008)	2.68 (0.912)	-2.12 (1.008)
	Median			3.00	-2.00	2.50	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 4	-4, -1	1, 5	-4, -1	1, 5	-4, -1	1, 5	-4, -1

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 20	n	19	19							19	19
	Mean (SD)	2.47 (0.612)	-1.37 (1.012)							2.47 (0.612)	-1.37 (1.012)
	Median	2.00	-1.00							2.00	-1.00
	Min, Max	2, 4	-4, 0							2, 4	-4, 0
On-treatment Week 22	n			17	17	15	15	32	32	32	32
	Mean (SD)			2.41 (0.712)	-2.18 (0.883)	2.47 (0.915)	-2.47 (0.915)	2.44 (0.801)	-2.31 (0.896)	2.44 (0.801)	-2.31 (0.896)
	Median			2.00	-2.00	2.00	-2.00	2.00	-2.00	2.00	-2.00
	Min, Max			1, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1
On-treatment Week 24	n	19	19							19	19
	Mean (SD)	2.32 (0.671)	-1.53 (1.020)							2.32 (0.671)	-1.53 (1.020)
	Median	2.00	-2.00							2.00	-2.00
	Min, Max	1, 4	-4, 0							1, 4	-4, 0
On-treatment Week 26	n			17	17	14	14	31	31	31	31
	Mean (SD)			2.35 (0.786)	-2.24 (0.903)	2.50 (0.941)	-2.50 (0.941)	2.42 (0.848)	-2.35 (0.915)	2.42 (0.848)	-2.35 (0.915)
	Median			2.00	-2.00	2.00	-2.50	2.00	-2.00	2.00	-2.00
	Min, Max			1, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1
On-treatment Week 28	n	16	16							16	16

Country: Philippines		PLCB-to-FLEX DOSE (N = 22)		40MG-to-FLEX DOSE (N = 22)		80MG-to-FLEX DOSE (N = 22)		Active-to-FLEX DOSE (N = 44)		Overall-to-FLEX DOSE (N = 66)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	2.38 (0.619)	-1.44 (1.094)							2.38 (0.619)	-1.44 (1.094)
	Median	2.00	-1.00							2.00	-1.00
	Min, Max	2, 4	-4, 0							2, 4	-4, 0
On-treatment Week 30	n			16	16	14	14	30	30	30	30
	Mean (SD)			2.31 (0.873)	-2.25 (0.775)	2.57 (1.089)	-2.43 (1.089)	2.43 (0.971)	-2.33 (0.922)	2.43 (0.971)	-2.33 (0.922)
	Median			2.00	-2.00	2.00	-2.50	2.00	-2.00	2.00	-2.00
	Min, Max			1, 5	-3, -1	1, 5	-4, 0	1, 5	-4, 0	1, 5	-4, 0
On-treatment Week 34	n			14	14	15	15	29	29	29	29
	Mean (SD)			2.14 (0.535)	-2.36 (0.745)	2.33 (0.816)	-2.60 (0.828)	2.24 (0.689)	-2.48 (0.785)	2.24 (0.689)	-2.48 (0.785)
	Median			2.00	-2.50	2.00	-3.00	2.00	-3.00	2.00	-3.00
	Min, Max			1, 3	-3, -1	1, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1
On-treatment (LOCF)	n	22	22	22	22	22	22	44	44	66	66
	Mean (SD)	2.55 (0.963)	-1.45 (1.101)	2.86 (1.457)	-1.95 (0.999)	2.68 (1.211)	-2.18 (1.097)	2.77 (1.327)	-2.07 (1.043)	2.70 (1.215)	-1.86 (1.094)
	Median	2.00	-1.50	2.00	-2.00	2.00	-2.00	2.00	-2.00	2.00	-2.00
	Min, Max	2, 6	-4, 0	1, 7	-3, 0	1, 6	-4, 0	1, 7	-4, 0	1, 7	-4, 0

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	10		13		12		25		35	
	Mean (SD)	3.90 (0.876)		4.92 (0.760)		4.67 (0.778)		4.80 (0.764)		4.54 (0.886)	
	Median	4.00		5.00		4.50		5.00		4.00	
	Min, Max	3, 6		4, 6		4, 6		4, 6		3, 6	
On-treatment Week 1	n	10	10	13	13	12	12	25	25	35	35
	Mean (SD)	3.90 (0.876)	0.00 (0.471)	4.92 (0.760)	0.00 (0.408)	4.50 (0.905)	-0.17 (0.389)	4.72 (0.843)	-0.08 (0.400)	4.49 (0.919)	-0.06 (0.416)
	Median	4.00	0.00	5.00	0.00	4.00	0.00	5.00	0.00	4.00	0.00
	Min, Max	3, 6	-1, 1	4, 6	-1, 1	3, 6	-1, 0	3, 6	-1, 1	3, 6	-1, 1
On-treatment Week 2	n	10	10	12	12	12	12	24	24	34	34
	Mean (SD)	3.80 (1.135)	-0.10 (0.876)	4.83 (0.718)	-0.08 (0.289)	4.33 (0.985)	-0.33 (0.492)	4.58 (0.881)	-0.21 (0.415)	4.35 (1.012)	-0.18 (0.576)
	Median	4.00	0.00	5.00	0.00	4.00	0.00	4.50	0.00	4.00	0.00
	Min, Max	2, 6	-2, 1	4, 6	-1, 0	3, 6	-1, 0	3, 6	-1, 0	2, 6	-2, 1
On-treatment Week 4	n	10	10	12	12	12	12	24	24	34	34
	Mean (SD)	3.70 (1.160)	-0.20 (0.789)	4.25 (0.866)	-0.67 (0.651)	4.17 (1.030)	-0.50 (0.674)	4.21 (0.932)	-0.58 (0.654)	4.06 (1.013)	-0.47 (0.706)
	Median	3.50	0.00	4.00	-1.00	4.00	0.00	4.00	-0.50	4.00	0.00
	Min, Max	2, 6	-2, 1	3, 6	-2, 0	2, 6	-2, 0	2, 6	-2, 0	2, 6	-2, 1
On-treatment Week 6	n			12	12	12	12	24	24	24	24

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			4.17 (1.030)	-0.75 (0.622)	4.08 (1.084)	-0.58 (0.793)	4.13 (1.035)	-0.67 (0.702)	4.13 (1.035)	-0.67 (0.702)
	Median			4.00	-1.00	4.00	0.00	4.00	-1.00	4.00	-1.00
	Min, Max			3, 6	-2, 0	2, 6	-2, 0	2, 6	-2, 0	2, 6	-2, 0
On-treatment Week 7	n			12	12	11	11	23	23	23	23
	Mean (SD)			4.00 (1.044)	-0.92 (0.669)	4.00 (1.000)	-0.73 (0.786)	4.00 (1.000)	-0.83 (0.717)	4.00 (1.000)	-0.83 (0.717)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			3, 6	-2, 0	2, 5	-2, 0	2, 6	-2, 0	2, 6	-2, 0
On-treatment Week 8	n	8	8	11	11	11	11	22	22	30	30
	Mean (SD)	3.13 (0.641)	-0.50 (0.756)	4.18 (1.250)	-0.82 (0.982)	4.00 (1.000)	-0.73 (0.786)	4.09 (1.109)	-0.77 (0.869)	3.83 (1.085)	-0.70 (0.837)
	Median	3.00	0.00	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	2, 4	-2, 0	3, 7	-2, 1	2, 5	-2, 0	2, 7	-2, 1	2, 7	-2, 1
On-treatment Week 10	n			11	11	11	11	22	22	22	22
	Mean (SD)			4.09 (1.300)	-0.91 (0.831)	3.91 (1.136)	-0.82 (0.874)	4.00 (1.195)	-0.86 (0.834)	4.00 (1.195)	-0.86 (0.834)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			3, 7	-2, 1	2, 6	-2, 1	2, 7	-2, 1	2, 7	-2, 1
On-treatment Week 12	n	8	8							8	8
	Mean (SD)	3.00 (0.000)	-0.63 (0.518)							3.00 (0.000)	-0.63 (0.518)
	Median	3.00	-1.00							3.00	-1.00

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	3, 3	-1, 0							3, 3	-1, 0
On-treatment Week 14	n			8	8	10	10	18	18	18	18
	Mean (SD)			3.75 (0.886)	-1.00 (0.535)	3.60 (1.174)	-1.10 (0.994)	3.67 (1.029)	-1.06 (0.802)	3.67 (1.029)	-1.06 (0.802)
	Median			3.50	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			3, 5	-2, 0	1, 5	-3, 0	1, 5	-3, 0	1, 5	-3, 0
On-treatment Week 16	n	8	8							8	8
	Mean (SD)	3.38 (0.518)	-0.25 (0.707)							3.38 (0.518)	-0.25 (0.707)
	Median	3.00	0.00							3.00	0.00
	Min, Max	3, 4	-1, 1							3, 4	-1, 1
On-treatment Week 18	n			6	6	9	9	15	15	15	15
	Mean (SD)			3.33 (0.516)	-1.17 (0.408)	3.33 (1.225)	-1.33 (0.866)	3.33 (0.976)	-1.27 (0.704)	3.33 (0.976)	-1.27 (0.704)
	Median			3.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			3, 4	-2, -1	1, 5	-3, 0	1, 5	-3, 0	1, 5	-3, 0
On-treatment Week 20	n	8	8							8	8
	Mean (SD)	3.38 (0.744)	-0.25 (1.035)							3.38 (0.744)	-0.25 (1.035)
	Median	3.00	-0.50							3.00	-0.50
	Min, Max	3, 5	-1, 2							3, 5	-1, 2

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 22	n			6	6	9	9	15	15	15	15
	Mean (SD)			3.33 (0.516)	-1.17 (0.408)	3.33 (1.000)	-1.33 (0.500)	3.33 (0.816)	-1.27 (0.458)	3.33 (0.816)	-1.27 (0.458)
	Median			3.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			3, 4	-2, -1	2, 5	-2, -1	2, 5	-2, -1	2, 5	-2, -1
On-treatment Week 24	n	8	8							8	8
	Mean (SD)	3.25 (0.707)	-0.38 (1.061)							3.25 (0.707)	-0.38 (1.061)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	3, 5	-1, 2							3, 5	-1, 2
On-treatment Week 26	n			6	6	9	9	15	15	15	15
	Mean (SD)			3.67 (0.816)	-1.00 (0.000)	3.22 (1.202)	-1.44 (0.726)	3.40 (1.056)	-1.27 (0.594)	3.40 (1.056)	-1.27 (0.594)
	Median			3.50	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			3, 5	-1, -1	1, 5	-3, -1	1, 5	-3, -1	1, 5	-3, -1
On-treatment Week 28	n	8	8							8	8
	Mean (SD)	3.38 (0.744)	-0.25 (1.035)							3.38 (0.744)	-0.25 (1.035)
	Median	3.00	-0.50							3.00	-0.50
	Min, Max	3, 5	-1, 2							3, 5	-1, 2
On-treatment Week 30	n			5	5	8	8	13	13	13	13

Country: Russia		PLCB-to-FLEX DOSE (N = 10)		40MG-to-FLEX DOSE (N = 13)		80MG-to-FLEX DOSE (N = 12)		Active-to-FLEX DOSE (N = 25)		Overall-to-FLEX DOSE (N = 35)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			3.20 (0.447)	-1.20 (0.447)	3.00 (1.069)	-1.50 (0.756)	3.08 (0.862)	-1.38 (0.650)	3.08 (0.862)	-1.38 (0.650)
	Median			3.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			3, 4	-2, -1	1, 5	-3, -1	1, 5	-3, -1	1, 5	-3, -1
On-treatment Week 34	n			5	5	9	9	14	14	14	14
	Mean (SD)			3.20 (0.447)	-1.20 (0.447)	3.22 (1.302)	-1.44 (0.726)	3.21 (1.051)	-1.36 (0.633)	3.21 (1.051)	-1.36 (0.633)
	Median			3.00	-1.00	3.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max			3, 4	-2, -1	1, 5	-3, -1	1, 5	-3, -1	1, 5	-3, -1
On-treatment (LOCF)	n	10	10	13	13	12	12	25	25	35	35
	Mean (SD)	3.80 (1.135)	-0.10 (0.994)	4.31 (1.251)	-0.62 (0.870)	3.50 (1.382)	-1.17 (0.937)	3.92 (1.352)	-0.88 (0.927)	3.89 (1.278)	-0.66 (0.998)
	Median	3.00	0.00	4.00	-1.00	3.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	3, 6	-1, 2	3, 7	-2, 1	1, 6	-3, 1	1, 7	-3, 1	1, 7	-3, 2

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	5		15		17		32		37	
	Mean (SD)	4.60 (1.517)		4.67 (0.724)		5.12 (0.928)		4.91 (0.856)		4.86 (0.948)	
	Median	5.00		5.00		5.00		5.00		5.00	
	Min, Max	3, 6		4, 6		4, 7		4, 7		3, 7	

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 1	n	5	5	15	15	17	17	32	32	37	37
	Mean (SD)	4.60 (1.517)	0.00 (0.000)	4.20 (0.941)	-0.47 (0.743)	4.47 (0.874)	-0.65 (0.702)	4.34 (0.902)	-0.56 (0.716)	4.38 (0.982)	-0.49 (0.692)
	Median	5.00	0.00	4.00	0.00	4.00	-1.00	4.00	-0.50	4.00	0.00
	Min, Max	3, 6	0, 0	2, 6	-2, 1	3, 6	-2, 0	2, 6	-2, 1	2, 6	-2, 1
On-treatment Week 2	n	5	5	14	14	16	16	30	30	35	35
	Mean (SD)	4.60 (1.517)	0.00 (0.000)	3.57 (0.852)	-1.07 (0.730)	3.75 (1.000)	-1.31 (0.793)	3.67 (0.922)	-1.20 (0.761)	3.80 (1.052)	-1.03 (0.822)
	Median	5.00	0.00	3.50	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	3, 6	0, 0	2, 5	-2, 0	2, 6	-3, 0	2, 6	-3, 0	2, 6	-3, 0
On-treatment Week 4	n	5	5	14	14	15	15	29	29	34	34
	Mean (SD)	4.20 (1.643)	-0.40 (0.548)	3.64 (1.082)	-1.00 (0.961)	3.47 (1.060)	-1.60 (0.986)	3.55 (1.055)	-1.31 (1.004)	3.65 (1.152)	-1.18 (0.999)
	Median	5.00	0.00	4.00	-1.00	4.00	-2.00	4.00	-1.00	4.00	-1.00
	Min, Max	2, 6	-1, 0	1, 5	-3, 0	2, 6	-3, 0	1, 6	-3, 0	1, 6	-3, 0
On-treatment Week 6	n			13	13	15	15	28	28	28	28
	Mean (SD)			3.62 (1.325)	-1.00 (1.000)	3.20 (0.775)	-1.87 (0.834)	3.39 (1.066)	-1.46 (0.999)	3.39 (1.066)	-1.46 (0.999)
	Median			4.00	-1.00	3.00	-2.00	3.00	-1.00	3.00	-1.00
	Min, Max			1, 6	-3, 0	2, 5	-3, -1	1, 6	-3, 0	1, 6	-3, 0
On-treatment Week 7	n			10	10	14	14	24	24	24	24

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			3.20 (1.317)	-1.30 (0.949)	3.50 (0.941)	-1.64 (1.082)	3.38 (1.096)	-1.50 (1.022)	3.38 (1.096)	-1.50 (1.022)
	Median			3.00	-1.00	3.00	-1.50	3.00	-1.00	3.00	-1.00
	Min, Max			1, 5	-3, 0	2, 5	-3, 0	1, 5	-3, 0	1, 5	-3, 0
On-treatment Week 8	n	5	5	9	9	14	14	23	23	28	28
	Mean (SD)	4.20 (1.483)	-0.40 (0.894)	3.00 (1.225)	-1.44 (0.882)	3.43 (1.158)	-1.71 (1.383)	3.26 (1.176)	-1.61 (1.196)	3.43 (1.260)	-1.39 (1.227)
	Median	4.00	-1.00	3.00	-1.00	3.00	-1.50	3.00	-1.00	3.00	-1.00
	Min, Max	2, 6	-1, 1	1, 5	-3, 0	2, 5	-4, 1	1, 5	-4, 1	1, 6	-4, 1
On-treatment Week 10	n			9	9	13	13	22	22	22	22
	Mean (SD)			3.00 (0.707)	-1.44 (0.726)	3.08 (0.954)	-1.92 (1.441)	3.05 (0.844)	-1.73 (1.202)	3.05 (0.844)	-1.73 (1.202)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-2, 0	1, 5	-4, 1	1, 5	-4, 1	1, 5	-4, 1
On-treatment Week 12	n	4	4							4	4
	Mean (SD)	3.50 (1.000)	-0.75 (1.258)							3.50 (1.000)	-0.75 (1.258)
	Median	4.00	-1.00							4.00	-1.00
	Min, Max	2, 4	-2, 1							2, 4	-2, 1
On-treatment Week 14	n			9	9	13	13	22	22	22	22
	Mean (SD)			3.22 (1.202)	-1.22 (0.833)	2.92 (0.954)	-2.08 (1.382)	3.05 (1.046)	-1.73 (1.241)	3.05 (1.046)	-1.73 (1.241)
	Median			3.00	-1.00	3.00	-2.00	3.00	-1.50	3.00	-1.50

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max			2, 6	-2, 0	1, 4	-4, 0	1, 6	-4, 0	1, 6	-4, 0
On-treatment Week 16	n	4	4							4	4
	Mean (SD)	3.25 (0.957)	-1.00 (0.816)							3.25 (0.957)	-1.00 (0.816)
	Median	3.50	-1.00							3.50	-1.00
	Min, Max	2, 4	-2, 0							2, 4	-2, 0
On-treatment Week 18	n			6	6	13	13	19	19	19	19
	Mean (SD)			2.50 (0.548)	-1.67 (0.516)	3.08 (0.760)	-1.92 (1.188)	2.89 (0.737)	-1.84 (1.015)	2.89 (0.737)	-1.84 (1.015)
	Median			2.50	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 3	-2, -1	1, 4	-4, 0	1, 4	-4, 0	1, 4	-4, 0
On-treatment Week 20	n	4	4							4	4
	Mean (SD)	3.75 (1.258)	-0.50 (1.732)							3.75 (1.258)	-0.50 (1.732)
	Median	4.00	-1.00							4.00	-1.00
	Min, Max	2, 5	-2, 2							2, 5	-2, 2
On-treatment Week 22	n			6	6	13	13	19	19	19	19
	Mean (SD)			3.00 (1.095)	-1.17 (0.753)	3.00 (0.577)	-2.00 (1.155)	3.00 (0.745)	-1.74 (1.098)	3.00 (0.745)	-1.74 (1.098)
	Median			3.00	-1.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 5	-2, 0	2, 4	-4, 0	2, 5	-4, 0	2, 5	-4, 0

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 24	n	4	4							4	4
	Mean (SD)	4.00 (1.633)	-0.25 (2.217)							4.00 (1.633)	-0.25 (2.217)
	Median	4.00	-1.00							4.00	-1.00
	Min, Max	2, 6	-2, 3							2, 6	-2, 3
On-treatment Week 26	n			5	5	12	12	17	17	17	17
	Mean (SD)			2.20 (0.837)	-1.80 (0.837)	2.92 (0.669)	-2.17 (1.030)	2.71 (0.772)	-2.06 (0.966)	2.71 (0.772)	-2.06 (0.966)
	Median			2.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 3	-3, -1	2, 4	-4, -1	1, 4	-4, -1	1, 4	-4, -1
On-treatment Week 28	n	3	3							3	3
	Mean (SD)	3.33 (1.155)	-1.33 (0.577)							3.33 (1.155)	-1.33 (0.577)
	Median	4.00	-1.00							4.00	-1.00
	Min, Max	2, 4	-2, -1							2, 4	-2, -1
On-treatment Week 30	n			5	5	12	12	17	17	17	17
	Mean (SD)			2.20 (0.837)	-1.80 (0.837)	2.92 (0.793)	-2.17 (1.193)	2.71 (0.849)	-2.06 (1.088)	2.71 (0.849)	-2.06 (1.088)
	Median			2.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 3	-3, -1	1, 4	-5, -1	1, 4	-5, -1	1, 4	-5, -1
On-treatment Week 34	n			5	5	11	11	16	16	16	16

Country: Taiwan		PLCB-to-FLEX DOSE (N = 5)		40MG-to-FLEX DOSE (N = 15)		80MG-to-FLEX DOSE (N = 17)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 37)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)			2.00 (0.707)	-2.00 (0.707)	2.82 (0.751)	-2.27 (1.272)	2.56 (0.814)	-2.19 (1.109)	2.56 (0.814)	-2.19 (1.109)
	Median			2.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			1, 3	-3, -1	1, 4	-5, -1	1, 4	-5, -1	1, 4	-5, -1
On-treatment (LOCF)	n	5	5	15	15	17	17	32	32	37	37
	Mean (SD)	4.40 (1.673)	-0.20 (1.924)	3.67 (1.496)	-1.00 (1.134)	3.41 (1.176)	-1.71 (1.359)	3.53 (1.319)	-1.38 (1.289)	3.65 (1.379)	-1.22 (1.417)
	Median	4.00	-1.00	4.00	-1.00	3.00	-1.00	3.00	-1.00	4.00	-1.00
	Min, Max	2, 6	-2, 3	1, 6	-3, 1	1, 6	-5, 0	1, 6	-5, 1	1, 6	-5, 3

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Baseline	n	13		17		15		32		45	
	Mean (SD)	4.08 (0.954)		4.65 (0.606)		4.87 (0.352)		4.75 (0.508)		4.56 (0.725)	
	Median	4.00		5.00		5.00		5.00		5.00	
	Min, Max	3, 5		4, 6		4, 5		4, 6		3, 6	
On-treatment Week 1	n	12	12	17	17	15	15	32	32	44	44
	Mean (SD)	3.92 (0.900)	-0.08 (0.289)	4.53 (0.717)	-0.12 (0.332)	4.53 (0.516)	-0.33 (0.488)	4.53 (0.621)	-0.22 (0.420)	4.36 (0.750)	-0.18 (0.390)
	Median	4.00	0.00	5.00	0.00	5.00	0.00	5.00	0.00	4.00	0.00
	Min, Max	3, 5	-1, 0	3, 6	-1, 0	4, 5	-1, 0	3, 6	-1, 0	3, 6	-1, 0

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 2	n	12	12	17	17	15	15	32	32	44	44
	Mean (SD)	3.50 (0.905)	-0.50 (0.674)	4.29 (0.849)	-0.35 (0.493)	4.13 (0.516)	-0.73 (0.594)	4.22 (0.706)	-0.53 (0.567)	4.02 (0.821)	-0.52 (0.590)
	Median	3.00	0.00	4.00	0.00	4.00	-1.00	4.00	-0.50	4.00	0.00
	Min, Max	2, 5	-2, 0	3, 6	-1, 0	3, 5	-2, 0	3, 6	-2, 0	2, 6	-2, 0
On-treatment Week 4	n	12	12	17	17	15	15	32	32	44	44
	Mean (SD)	3.17 (0.937)	-0.83 (0.835)	4.00 (0.791)	-0.65 (0.606)	4.20 (0.676)	-0.67 (0.724)	4.09 (0.734)	-0.66 (0.653)	3.84 (0.888)	-0.70 (0.701)
	Median	3.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max	1, 5	-2, 0	3, 6	-2, 0	3, 5	-2, 0	3, 6	-2, 0	1, 6	-2, 0
On-treatment Week 6	n			17	17	15	15	32	32	32	32
	Mean (SD)			3.76 (0.831)	-0.88 (0.600)	4.20 (0.775)	-0.67 (0.900)	3.97 (0.822)	-0.78 (0.751)	3.97 (0.822)	-0.78 (0.751)
	Median			4.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			3, 6	-2, 0	3, 5	-2, 1	3, 6	-2, 1	3, 6	-2, 1
On-treatment Week 7	n			16	16	15	15	31	31	31	31
	Mean (SD)			3.50 (0.966)	-1.13 (0.806)	3.93 (0.704)	-0.93 (0.799)	3.71 (0.864)	-1.03 (0.795)	3.71 (0.864)	-1.03 (0.795)
	Median			3.00	-1.00	4.00	-1.00	4.00	-1.00	4.00	-1.00
	Min, Max			2, 6	-2, 0	3, 5	-2, 0	2, 6	-2, 0	2, 6	-2, 0
On-treatment Week 8	n	12	12	16	16	15	15	31	31	43	43

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	2.83 (0.718)	-1.17 (0.835)	3.50 (1.033)	-1.13 (0.885)	3.73 (0.799)	-1.13 (0.834)	3.61 (0.919)	-1.13 (0.846)	3.40 (0.929)	-1.14 (0.833)
	Median	3.00	-1.00	3.00	-1.00	4.00	-1.00	3.00	-1.00	3.00	-1.00
	Min, Max	1, 4	-2, 0	2, 6	-2, 0	3, 5	-2, 0	2, 6	-2, 0	1, 6	-2, 0
On-treatment Week 10	n			14	14	15	15	29	29	29	29
	Mean (SD)			3.00 (0.679)	-1.50 (0.855)	3.53 (0.915)	-1.33 (0.816)	3.28 (0.841)	-1.41 (0.825)	3.28 (0.841)	-1.41 (0.825)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-2, 0	2, 5	-2, 0	2, 5	-2, 0	2, 5	-2, 0
On-treatment Week 12	n	12	12							12	12
	Mean (SD)	2.75 (0.622)	-1.25 (0.866)							2.75 (0.622)	-1.25 (0.866)
	Median	3.00	-1.50							3.00	-1.50
	Min, Max	1, 3	-2, 0							1, 3	-2, 0
On-treatment Week 14	n			14	14	15	15	29	29	29	29
	Mean (SD)			3.00 (0.679)	-1.50 (0.650)	3.20 (0.775)	-1.67 (0.724)	3.10 (0.724)	-1.59 (0.682)	3.10 (0.724)	-1.59 (0.682)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-2, 0	2, 5	-3, 0	2, 5	-3, 0	2, 5	-3, 0
On-treatment Week 16	n	11	11							11	11
	Mean (SD)	2.73 (0.647)	-1.36 (0.809)							2.73 (0.647)	-1.36 (0.809)
	Median	3.00	-2.00							3.00	-2.00

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Min, Max	1, 3	-2, 0							1, 3	-2, 0
On-treatment Week 18	n			14	14	15	15	29	29	29	29
	Mean (SD)			2.79 (0.579)	-1.71 (0.611)	3.20 (0.676)	-1.67 (0.617)	3.00 (0.655)	-1.69 (0.604)	3.00 (0.655)	-1.69 (0.604)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-3, -1	2, 5	-2, 0	2, 5	-3, 0	2, 5	-3, 0
On-treatment Week 20	n	11	11							11	11
	Mean (SD)	2.82 (0.751)	-1.27 (0.786)							2.82 (0.751)	-1.27 (0.786)
	Median	3.00	-1.00							3.00	-1.00
	Min, Max	1, 4	-2, 0							1, 4	-2, 0
On-treatment Week 22	n			14	14	14	14	28	28	28	28
	Mean (SD)			2.71 (0.469)	-1.79 (0.579)	3.07 (0.730)	-1.79 (0.699)	2.89 (0.629)	-1.79 (0.630)	2.89 (0.629)	-1.79 (0.630)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 3	-3, -1	2, 5	-3, 0	2, 5	-3, 0	2, 5	-3, 0
On-treatment Week 24	n	11	11							11	11
	Mean (SD)	2.73 (0.647)	-1.36 (0.809)							2.73 (0.647)	-1.36 (0.809)
	Median	3.00	-2.00							3.00	-2.00
	Min, Max	1, 3	-2, 0							1, 3	-2, 0

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
On-treatment Week 26	n			14	14	13	13	27	27	27	27
	Mean (SD)			2.79 (0.579)	-1.71 (0.611)	2.92 (0.277)	-1.92 (0.277)	2.85 (0.456)	-1.81 (0.483)	2.85 (0.456)	-1.81 (0.483)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-3, -1	2, 3	-2, -1	2, 4	-3, -1	2, 4	-3, -1
On-treatment Week 28	n	11	11							11	11
	Mean (SD)	2.73 (0.647)	-1.36 (0.809)							2.73 (0.647)	-1.36 (0.809)
	Median	3.00	-2.00							3.00	-2.00
	Min, Max	1, 3	-2, 0							1, 3	-2, 0
On-treatment Week 30	n			12	12	13	13	25	25	25	25
	Mean (SD)			2.75 (0.452)	-1.67 (0.651)	2.92 (0.277)	-1.92 (0.494)	2.84 (0.374)	-1.80 (0.577)	2.84 (0.374)	-1.80 (0.577)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 3	-3, -1	2, 3	-3, -1	2, 3	-3, -1	2, 3	-3, -1
On-treatment Week 34	n			13	13	13	13	26	26	26	26
	Mean (SD)			2.85 (0.555)	-1.62 (0.650)	2.92 (0.277)	-1.92 (0.494)	2.88 (0.431)	-1.77 (0.587)	2.88 (0.431)	-1.77 (0.587)
	Median			3.00	-2.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max			2, 4	-3, -1	2, 3	-3, -1	2, 4	-3, -1	2, 4	-3, -1
On-treatment (LOCF)	n	12	12	17	17	15	15	32	32	44	44

Country: Ukraine		PLCB-to-FLEX DOSE (N = 13)		40MG-to-FLEX DOSE (N = 17)		80MG-to-FLEX DOSE (N = 15)		Active-to-FLEX DOSE (N = 32)		Overall-to-FLEX DOSE (N = 45)	
Visit	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change	Observed	Change
	Mean (SD)	2.75 (0.622)	-1.25 (0.866)	3.29 (1.047)	-1.35 (0.786)	3.20 (0.775)	-1.67 (0.816)	3.25 (0.916)	-1.50 (0.803)	3.11 (0.868)	-1.43 (0.818)
	Median	3.00	-1.50	3.00	-1.00	3.00	-2.00	3.00	-2.00	3.00	-2.00
	Min, Max	1, 3	-2, 0	2, 6	-3, 0	2, 5	-3, 0	2, 6	-3, 0	1, 6	-3, 0

On-treatment baseline is the last observation on or before the first dose date of DSP-5423P. On-treatment (LOCF) is the last post-baseline observation in the DSP-5423P treated period up to 7 days after final application of the study treatment. Summary statistics for the observed value and the change from baseline values are based on subjects with both a baseline and the target visit observation. The final data at Open-Week 52 was used.

2.7.3.6.3　40 試験

表 2.7.3.6-41　PANSS サブスケール別合計スコア変化量
（40 試験：ロナセンテープ貼付期）

安全性解析対象集団

			Cohort 1 (N = 97)		Cohort 2 (N = 103)	
Subscale	Visit	Statistics	Observed	Change	Observed	Change
Positive subscale	Baseline	n	97		103	
		Mean (SD)	13.4 (5.46)		14.8 (5.61)	
		Median	13.0		14.0	
		Min, Max	7, 30		7, 29	
	Week 1	n	97	97	103	103
		Mean (SD)	13.3 (5.38)	-0.1 (1.06)	14.5 (5.54)	-0.3 (1.44)
		Median	13.0	0.0	14.0	0.0
		Min, Max	7, 30	-3, 5	7, 31	-5, 5
	Week 2	n	89	89	100	100
		Mean (SD)	13.1 (5.33)	0.0 (1.51)	14.4 (5.59)	-0.5 (2.07)
		Median	13.0	0.0	14.0	0.0
		Min, Max	7, 31	-4, 7	7, 32	-7, 10
	Week 4	n	87	87	99	99
		Mean (SD)	13.3 (5.36)	0.0 (1.25)	13.9 (5.74)	-0.9 (2.29)
		Median	13.0	0.0	13.0	0.0
		Min, Max	7, 31	-5, 4	7, 34	-8, 5
	Week 6	n	80	80	95	95
		Mean (SD)	13.5 (5.59)	0.1 (2.28)	13.6 (5.28)	-1.1 (2.53)
		Median	14.0	0.0	13.0	0.0
		Min, Max	7, 33	-3, 16	7, 28	-11, 9
	Week 8	n	78	78	90	90
		Mean (SD)	13.4 (5.86)	0.0 (3.00)	13.2 (5.27)	-1.4 (2.64)
		Median	13.0	0.0	12.0	0.0
		Min, Max	7, 32	-6, 20	7, 29	-9, 3
	Week 12	n	75	75	88	88
		Mean (SD)	13.1 (5.29)	-0.2 (2.06)	13.0 (4.92)	-1.6 (2.84)
		Median	13.0	0.0	12.0	-1.0
		Min, Max	7, 30	-6, 7	7, 28	-10, 7
	Week 16	n	71	71	82	82

Subscale	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
		Mean (SD)	12.4 (4.90)	-0.5 (1.80)	13.0 (5.04)	-1.7 (3.17)
		Median	11.0	0.0	12.0	-0.5
		Min, Max	7, 29	-7, 4	7, 28	-12, 5
	Week 20	n	69	69	78	78
		Mean (SD)	12.5 (4.86)	-0.3 (2.17)	13.2 (5.33)	-1.4 (3.76)
		Median	12.0	0.0	12.0	-1.0
		Min, Max	7, 25	-7, 7	7, 28	-11, 10
	Week 24	n	67	67	72	72
		Mean (SD)	12.4 (4.91)	-0.5 (2.30)	12.9 (5.27)	-1.8 (3.41)
		Median	11.0	0.0	12.0	-1.0
		Min, Max	7, 25	-7, 8	7, 28	-11, 8
	Week 28	n	67	67	69	69
		Mean (SD)	13.0 (5.60)	0.1 (2.99)	12.6 (5.02)	-1.8 (3.40)
		Median	12.0	0.0	11.0	-1.0
		Min, Max	7, 28	-7, 13	7, 27	-12, 5
	Week 36	n	63	63	67	67
		Mean (SD)	12.1 (4.78)	-0.6 (2.19)	12.9 (5.26)	-1.4 (4.02)
		Median	12.0	0.0	11.0	-1.0
		Min, Max	7, 27	-8, 5	7, 27	-12, 11
	Week 44	n	60	60	61	61
		Mean (SD)	12.4 (5.10)	-0.2 (2.96)	12.5 (5.29)	-1.8 (3.73)
		Median	12.0	0.0	11.0	-1.0
		Min, Max	7, 25	-11, 8	7, 29	-12, 10
	Week 52	n	57	57	60	60
		Mean (SD)	12.1 (4.88)	-0.5 (2.70)	12.1 (5.35)	-2.1 (4.18)
		Median	11.0	0.0	10.5	-1.0
		Min, Max	7, 24	-13, 6	7, 31	-16, 9
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	13.9 (6.41)	0.5 (4.01)	14.1 (6.31)	-0.7 (4.55)
		Median	13.0	0.0	13.0	0.0
		Min, Max	7, 31	-13, 20	7, 34	-16, 11
Negative subscale	Baseline	n	97		103	
		Mean (SD)	17.5 (6.95)		18.4 (7.51)	

Subscale	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
		Median	17.0		18.0	
		Min, Max	7, 38		7, 38	
	Week 1	n	97	97	103	103
		Mean (SD)	17.3 (6.91)	-0.2 (0.98)	18.1 (7.31)	-0.2 (1.70)
		Median	16.0	0.0	17.0	0.0
		Min, Max	7, 37	-4, 3	7, 40	-8, 4
	Week 2	n	89	89	100	100
		Mean (SD)	17.0 (6.62)	-0.3 (1.49)	18.0 (7.13)	-0.5 (1.98)
		Median	16.0	0.0	17.5	0.0
		Min, Max	7, 36	-5, 4	7, 40	-8, 5
	Week 4	n	87	87	99	99
		Mean (SD)	17.1 (6.56)	-0.4 (1.57)	17.4 (6.78)	-0.8 (2.44)
		Median	16.0	0.0	17.0	0.0
		Min, Max	7, 36	-7, 5	7, 40	-10, 4
	Week 6	n	80	80	95	95
		Mean (SD)	17.1 (6.64)	-0.5 (1.66)	17.0 (6.60)	-1.1 (2.49)
		Median	17.5	0.0	16.0	0.0
		Min, Max	7, 36	-5, 5	7, 37	-10, 4
	Week 8	n	78	78	90	90
		Mean (SD)	16.8 (6.74)	-0.7 (1.93)	16.9 (6.77)	-1.3 (3.03)
		Median	16.0	0.0	17.0	0.0
		Min, Max	7, 36	-6, 5	7, 37	-12, 6
	Week 12	n	75	75	88	88
		Mean (SD)	16.8 (6.75)	-0.7 (2.07)	16.6 (6.76)	-1.6 (3.12)
		Median	16.0	0.0	16.0	-0.5
		Min, Max	7, 36	-6, 5	7, 37	-13, 6
	Week 16	n	71	71	82	82
		Mean (SD)	16.1 (6.48)	-1.1 (2.08)	16.7 (6.89)	-1.9 (3.24)
		Median	16.0	0.0	15.5	-1.0
		Min, Max	7, 36	-7, 5	7, 37	-13, 6
	Week 20	n	69	69	78	78
		Mean (SD)	16.2 (6.51)	-0.9 (2.20)	16.4 (6.84)	-1.9 (3.38)
		Median	15.0	0.0	16.0	-1.0

Subscale	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
		Min, Max	7, 33	-9, 4	7, 37	-18, 6
	Week 24	n	67	67	72	72
		Mean (SD)	16.1 (6.68)	-1.1 (2.49)	16.5 (7.03)	-2.4 (4.06)
		Median	15.0	0.0	16.0	-1.0
		Min, Max	7, 33	-10, 5	7, 37	-20, 5
	Week 28	n	67	67	69	69
		Mean (SD)	16.2 (6.69)	-1.0 (3.12)	16.2 (6.89)	-2.5 (4.14)
		Median	15.0	0.0	15.0	-1.0
		Min, Max	7, 33	-11, 10	7, 37	-20, 6
	Week 36	n	63	63	67	67
		Mean (SD)	15.6 (6.52)	-1.2 (3.00)	16.1 (6.98)	-2.6 (4.29)
		Median	15.0	0.0	14.0	-1.0
		Min, Max	7, 33	-10, 5	7, 37	-21, 6
	Week 44	n	60	60	61	61
		Mean (SD)	15.5 (6.92)	-1.3 (2.91)	16.0 (7.23)	-2.5 (4.40)
		Median	14.5	0.0	14.0	-1.0
		Min, Max	7, 33	-11, 6	7, 37	-21, 4
	Week 52	n	57	57	60	60
		Mean (SD)	15.5 (6.64)	-1.3 (2.84)	15.4 (7.02)	-2.9 (4.70)
		Median	15.0	0.0	14.0	-1.0
		Min, Max	7, 32	-10, 5	7, 37	-21, 11
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	16.7 (6.84)	-0.8 (2.79)	16.8 (7.25)	-1.6 (4.35)
		Median	16.0	0.0	16.0	0.0
		Min, Max	7, 37	-10, 10	7, 40	-21, 11
General psychopathology subscale	Baseline	n	97		103	
		Mean (SD)	32.7 (11.13)		34.3 (10.30)	
		Median	33.0		34.0	
		Min, Max	16, 66		16, 57	
	Week 1	n	97	97	103	103
		Mean (SD)	32.5 (11.11)	-0.2 (2.09)	33.9 (10.23)	-0.4 (2.38)
		Median	32.0	0.0	34.0	0.0
		Min, Max	16, 66	-15, 4	16, 57	-12, 7

Subscale	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
	Week 2	n	89	89	100	100
		Mean (SD)	31.9 (10.21)	-0.3 (3.10)	34.0 (10.34)	-0.6 (3.36)
		Median	31.0	0.0	34.0	0.0
		Min, Max	16, 57	-17, 16	16, 57	-11, 18
	Week 4	n	87	87	99	99
		Mean (SD)	32.1 (10.29)	-0.4 (2.14)	33.3 (10.59)	-0.9 (3.89)
		Median	31.0	0.0	34.0	0.0
		Min, Max	16, 60	-10, 5	16, 63	-19, 9
	Week 6	n	80	80	95	95
		Mean (SD)	32.3 (10.66)	-0.2 (2.84)	32.7 (9.94)	-1.2 (3.86)
		Median	32.0	0.0	33.0	0.0
		Min, Max	16, 61	-9, 14	16, 57	-18, 8
	Week 8	n	78	78	90	90
		Mean (SD)	32.1 (11.41)	-0.2 (4.35)	32.0 (10.25)	-1.9 (4.84)
		Median	31.0	0.0	32.0	0.0
		Min, Max	16, 60	-9, 26	16, 59	-20, 10
	Week 12	n	75	75	88	88
		Mean (SD)	31.3 (10.81)	-0.9 (3.25)	32.1 (10.89)	-1.8 (5.98)
		Median	30.0	0.0	32.0	-1.0
		Min, Max	16, 58	-9, 10	16, 62	-23, 22
	Week 16	n	71	71	82	82
		Mean (SD)	30.4 (10.58)	-1.3 (3.58)	31.8 (10.44)	-2.5 (5.97)
		Median	28.0	0.0	31.5	-1.0
		Min, Max	16, 58	-9, 7	16, 62	-22, 10
	Week 20	n	69	69	78	78
		Mean (SD)	30.7 (11.01)	-0.8 (3.92)	31.5 (10.54)	-2.5 (6.00)
		Median	31.0	0.0	31.0	-1.0
		Min, Max	16, 59	-10, 10	16, 62	-20, 11
	Week 24	n	67	67	72	72
		Mean (SD)	30.0 (10.62)	-1.5 (3.98)	31.6 (11.20)	-3.1 (6.79)
		Median	28.0	0.0	31.5	-1.0
		Min, Max	16, 59	-11, 8	16, 64	-23, 10

Subscale	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
	Week 28	n	67	67	69	69
		Mean (SD)	31.1 (12.08)	-0.4 (5.93)	30.9 (10.39)	-3.5 (6.62)
		Median	28.0	0.0	30.0	-1.0
		Min, Max	16, 71	-12, 30	16, 57	-22, 5
	Week 36	n	63	63	67	67
		Mean (SD)	29.1 (9.56)	-1.7 (3.84)	30.4 (10.29)	-3.9 (7.49)
		Median	27.0	0.0	30.0	-1.0
		Min, Max	16, 55	-12, 4	16, 51	-22, 12
	Week 44	n	60	60	61	61
		Mean (SD)	29.1 (10.14)	-1.3 (4.67)	30.1 (10.95)	-3.8 (7.47)
		Median	26.5	0.0	29.0	-1.0
		Min, Max	16, 65	-15, 9	16, 57	-22, 15
	Week 52	n	57	57	60	60
		Mean (SD)	28.5 (9.62)	-1.7 (4.53)	29.5 (10.89)	-4.2 (7.77)
		Median	27.0	0.0	28.0	-2.0
		Min, Max	16, 64	-18, 8	16, 57	-24, 17
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	32.9 (12.21)	0.1 (6.38)	33.2 (11.99)	-1.1 (8.05)
		Median	32.0	0.0	32.0	0.0
		Min, Max	16, 71	-18, 30	16, 64	-24, 22

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-42　PANSS 5 因子モデル別合計スコア変化量
（40 試験：ロナセンテープ貼付期）

安全性解析対象集団

5 Factor	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
Negative symptoms	Baseline	n	97		103	
		Mean (SD)	15.2 (6.05)		16.0 (6.57)	
		Median	15.0		16.0	
		Min, Max	6, 32		6, 33	
	Week 1	n	97	97	103	103
		Mean (SD)	15.0 (6.09)	-0.1 (0.95)	15.8 (6.40)	-0.2 (1.47)
		Median	15.0	0.0	15.0	0.0

5 Factor	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
		Min, Max	6, 31	-4, 3	6, 35	-5, 4
	Week 2	n	89	89	100	100
		Mean (SD)	14.8 (5.85)	-0.2 (1.33)	15.7 (6.31)	-0.4 (1.81)
		Median	15.0	0.0	16.0	0.0
		Min, Max	6, 29	-5, 3	6, 35	-8, 4
	Week 4	n	87	87	99	99
		Mean (SD)	14.8 (5.77)	-0.3 (1.40)	15.2 (6.12)	-0.6 (2.22)
		Median	14.0	0.0	15.0	0.0
		Min, Max	6, 29	-6, 5	6, 35	-9, 4
	Week 6	n	80	80	95	95
		Mean (SD)	14.7 (5.72)	-0.5 (1.60)	14.7 (5.88)	-1.0 (2.18)
		Median	14.0	0.0	15.0	0.0
		Min, Max	6, 29	-6, 5	6, 30	-9, 4
	Week 8	n	78	78	90	90
		Mean (SD)	14.5 (5.85)	-0.6 (1.90)	14.6 (6.06)	-1.3 (2.70)
		Median	13.5	0.0	14.0	0.0
		Min, Max	6, 29	-6, 4	6, 30	-10, 6
	Week 12	n	75	75	88	88
		Mean (SD)	14.5 (5.98)	-0.7 (1.76)	14.4 (6.06)	-1.4 (2.83)
		Median	13.0	0.0	14.0	0.0
		Min, Max	6, 29	-6, 4	6, 30	-10, 7
	Week 16	n	71	71	82	82
		Mean (SD)	13.8 (5.53)	-1.0 (1.79)	14.5 (6.13)	-1.6 (2.98)
		Median	13.0	0.0	13.5	-0.5
		Min, Max	6, 29	-6, 4	6, 30	-12, 6
	Week 20	n	69	69	78	78
		Mean (SD)	14.0 (5.71)	-0.7 (1.91)	14.3 (5.93)	-1.6 (3.24)
		Median	13.0	0.0	14.0	-1.0
		Min, Max	6, 28	-8, 4	6, 30	-17, 7
	Week 24	n	67	67	72	72
		Mean (SD)	13.8 (5.82)	-0.9 (2.21)	14.2 (6.10)	-2.1 (3.72)
		Median	13.0	0.0	13.0	-1.0
		Min, Max	6, 28	-6, 4	6, 30	-18, 6

5 Factor	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
	Week 28	n	67	67	69	69
		Mean (SD)	14.1 (6.08)	-0.7 (2.60)	14.0 (5.96)	-2.2 (3.82)
		Median	13.0	0.0	13.0	-1.0
		Min, Max	6, 29	-7, 9	6, 30	-18, 7
	Week 36	n	63	63	67	67
		Mean (SD)	13.4 (5.71)	-1.0 (2.47)	13.8 (5.96)	-2.4 (3.82)
		Median	13.0	0.0	13.0	-1.0
		Min, Max	6, 28	-8, 5	6, 30	-19, 7
	Week 44	n	60	60	61	61
		Mean (SD)	13.2 (6.00)	-1.1 (2.44)	13.5 (6.16)	-2.3 (3.91)
		Median	12.0	-0.5	12.0	-1.0
		Min, Max	6, 29	-9, 5	6, 30	-19, 5
	Week 52	n	57	57	60	60
		Mean (SD)	13.1 (5.61)	-1.2 (2.36)	13.2 (6.05)	-2.6 (4.18)
		Median	13.0	-1.0	12.0	-1.0
		Min, Max	6, 28	-7, 5	6, 30	-19, 9
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	14.5 (6.05)	-0.7 (2.38)	14.5 (6.44)	-1.5 (3.96)
		Median	14.0	0.0	14.0	-1.0
		Min, Max	6, 31	-7, 9	6, 35	-19, 9
Excitement	Baseline	n	97		103	
		Mean (SD)	6.6 (2.56)		7.5 (2.69)	
		Median	6.0		7.0	
		Min, Max	4, 14		4, 15	
	Week 1	n	97	97	103	103
		Mean (SD)	6.6 (2.66)	0.0 (0.59)	7.4 (2.68)	0.0 (0.72)
		Median	6.0	0.0	7.0	0.0
		Min, Max	4, 17	-2, 3	4, 15	-3, 2
	Week 2	n	89	89	100	100
		Mean (SD)	6.5 (2.30)	0.0 (0.75)	7.5 (2.83)	0.0 (1.26)
		Median	6.0	0.0	7.5	0.0
		Min, Max	4, 13	-3, 3	4, 17	-3, 8

			Cohort 1 (N = 97)		Cohort 2 (N = 103)	
5 Factor	Visit	Statistics	Observed	Change	Observed	Change
	Week 4	n	87	87	99	99
		Mean (SD)	6.6 (2.39)	0.0 (0.75)	7.4 (2.91)	-0.1 (1.30)
		Median	7.0	0.0	7.0	0.0
		Min, Max	4, 13	-2, 2	4, 18	-5, 4
	Week 6	n	80	80	95	95
		Mean (SD)	6.7 (2.50)	0.1 (1.09)	7.3 (2.60)	-0.2 (1.26)
		Median	6.0	0.0	7.0	0.0
		Min, Max	4, 14	-2, 6	4, 15	-5, 5
	Week 8	n	78	78	90	90
		Mean (SD)	6.6 (2.59)	0.1 (1.25)	6.9 (2.57)	-0.4 (1.41)
		Median	6.0	0.0	6.0	0.0
		Min, Max	4, 15	-2, 8	4, 16	-6, 2
	Week 12	n	75	75	88	88
		Mean (SD)	6.6 (2.55)	0.0 (1.00)	6.9 (2.72)	-0.3 (1.65)
		Median	6.0	0.0	6.0	0.0
		Min, Max	4, 13	-2, 3	4, 18	-6, 4
	Week 16	n	71	71	82	82
		Mean (SD)	6.4 (2.51)	-0.1 (1.07)	6.8 (2.64)	-0.5 (1.74)
		Median	6.0	0.0	6.0	0.0
		Min, Max	4, 14	-4, 2	4, 17	-6, 3
	Week 20	n	69	69	78	78
		Mean (SD)	6.3 (2.52)	-0.1 (0.85)	6.9 (2.72)	-0.3 (2.08)
		Median	5.0	0.0	6.0	0.0
		Min, Max	4, 14	-3, 2	4, 18	-6, 6
	Week 24	n	67	67	72	72
		Mean (SD)	6.2 (2.63)	-0.2 (1.40)	6.7 (2.72)	-0.6 (2.03)
		Median	5.0	0.0	6.0	0.0
		Min, Max	4, 14	-6, 4	4, 19	-6, 5
	Week 28	n	67	67	69	69
		Mean (SD)	6.6 (2.87)	0.2 (1.40)	6.4 (2.34)	-0.8 (1.98)
		Median	5.0	0.0	6.0	0.0
		Min, Max	4, 17	-5, 3	4, 13	-6, 5
	Week 36	n	63	63	67	67

			Cohort 1 (N = 97)		Cohort 2 (N = 103)	
5 Factor	Visit	Statistics	Observed	Change	Observed	Change
		Mean (SD)	6.2 (2.46)	-0.1 (1.26)	6.5 (2.57)	-0.6 (2.35)
		Median	5.0	0.0	6.0	0.0
		Min, Max	4, 13	-5, 3	4, 13	-6, 6
	Week 44	n	60	60	61	61
		Mean (SD)	6.3 (2.71)	0.0 (1.36)	6.4 (2.56)	-0.7 (2.32)
		Median	5.0	0.0	6.0	0.0
		Min, Max	4, 16	-5, 5	4, 15	-6, 9
	Week 52	n	57	57	60	60
		Mean (SD)	6.1 (2.64)	-0.2 (1.41)	6.3 (2.43)	-0.9 (2.01)
		Median	5.0	0.0	6.0	0.0
		Min, Max	4, 16	-6, 5	4, 15	-7, 4
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	6.9 (3.07)	0.3 (1.74)	7.6 (3.45)	0.1 (2.56)
		Median	6.0	0.0	7.0	0.0
		Min, Max	4, 16	-6, 8	4, 19	-7, 9
Cognitive disorders	Baseline	n	97		103	
		Mean (SD)	10.2 (3.95)		10.6 (3.95)	
		Median	10.0		11.0	
		Min, Max	5, 20		5, 22	
	Week 1	n	97	97	103	103
		Mean (SD)	10.1 (3.82)	-0.1 (0.64)	10.6 (3.96)	0.0 (0.93)
		Median	10.0	0.0	11.0	0.0
		Min, Max	5, 18	-3, 2	5, 22	-4, 5
	Week 2	n	89	89	100	100
		Mean (SD)	10.1 (3.78)	-0.1 (0.89)	10.6 (3.84)	-0.1 (1.06)
		Median	10.0	0.0	11.0	0.0
		Min, Max	5, 20	-3, 3	5, 22	-4, 5
	Week 4	n	87	87	99	99
		Mean (SD)	10.1 (3.79)	-0.3 (0.92)	10.3 (3.97)	-0.3 (1.15)
		Median	10.0	0.0	11.0	0.0
		Min, Max	5, 21	-3, 3	5, 22	-5, 3
	Week 6	n	80	80	95	95
		Mean (SD)	10.3 (4.02)	-0.2 (1.07)	10.2 (3.82)	-0.3 (1.27)

5 Factor	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
		Median	10.0	0.0	11.0	0.0
		Min, Max	5, 24	-4, 6	5, 22	-5, 5
	Week 8	n	78	78	90	90
		Mean (SD)	10.3 (4.17)	-0.1 (1.54)	10.2 (3.91)	-0.4 (1.54)
		Median	10.0	0.0	10.0	0.0
		Min, Max	5, 23	-5, 8	5, 22	-5, 4
	Week 12	n	75	75	88	88
		Mean (SD)	9.9 (3.91)	-0.3 (1.44)	10.1 (4.01)	-0.5 (2.11)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 23	-5, 5	5, 22	-6, 12
	Week 16	n	71	71	82	82
		Mean (SD)	9.6 (3.85)	-0.4 (1.32)	10.0 (3.95)	-0.8 (1.74)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 22	-5, 4	5, 22	-7, 3
	Week 20	n	69	69	78	78
		Mean (SD)	9.6 (3.68)	-0.3 (1.18)	10.0 (4.17)	-0.8 (1.81)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 19	-4, 3	5, 22	-7, 4
	Week 24	n	67	67	72	72
		Mean (SD)	9.6 (3.86)	-0.4 (1.27)	10.2 (4.21)	-0.8 (1.94)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 20	-4, 2	5, 22	-7, 2
	Week 28	n	67	67	69	69
		Mean (SD)	9.7 (3.96)	-0.3 (2.14)	10.0 (4.11)	-0.9 (1.97)
		Median	8.0	0.0	10.0	0.0
		Min, Max	5, 19	-6, 11	5, 22	-7, 4
	Week 36	n	63	63	67	67
		Mean (SD)	9.3 (3.75)	-0.6 (1.55)	9.9 (4.02)	-0.9 (2.00)
		Median	8.0	0.0	10.0	0.0
		Min, Max	5, 18	-6, 2	5, 22	-7, 4
	Week 44	n	60	60	61	61
		Mean (SD)	9.5 (3.95)	-0.3 (1.58)	9.7 (4.10)	-1.0 (2.07)
		Median	8.0	0.0	9.0	0.0

5 Factor	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
		Min, Max	5, 19	-5, 3	5, 22	-7, 4
	Week 52	n	57	57	60	60
		Mean (SD)	9.3 (3.86)	-0.5 (1.56)	9.5 (4.02)	-1.2 (2.07)
		Median	8.0	0.0	9.0	-0.5
		Min, Max	5, 18	-6, 3	5, 22	-6, 5
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	10.1 (4.12)	-0.2 (2.04)	10.2 (4.08)	-0.4 (2.42)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 19	-6, 11	5, 22	-6, 12
Positive symptoms	Baseline	n	97		103	
		Mean (SD)	8.2 (3.66)		9.0 (3.70)	
		Median	8.0		8.0	
		Min, Max	4, 19		4, 18	
	Week 1	n	97	97	103	103
		Mean (SD)	8.2 (3.62)	0.0 (0.91)	8.7 (3.71)	-0.3 (1.10)
		Median	8.0	0.0	8.0	0.0
		Min, Max	4, 19	-2, 5	4, 19	-5, 4
	Week 2	n	89	89	100	100
		Mean (SD)	8.1 (3.69)	0.0 (1.22)	8.7 (3.66)	-0.3 (1.34)
		Median	8.0	0.0	8.0	0.0
		Min, Max	4, 19	-2, 7	4, 18	-5, 6
	Week 4	n	87	87	99	99
		Mean (SD)	8.2 (3.66)	0.0 (0.88)	8.4 (3.75)	-0.6 (1.58)
		Median	8.0	0.0	8.0	0.0
		Min, Max	4, 19	-2, 4	4, 20	-6, 6
	Week 6	n	80	80	95	95
		Mean (SD)	8.3 (3.86)	0.1 (1.51)	8.3 (3.52)	-0.7 (1.71)
		Median	8.0	0.0	8.0	0.0
		Min, Max	4, 19	-3, 9	4, 17	-6, 6
	Week 8	n	78	78	90	90
		Mean (SD)	8.2 (3.98)	0.1 (2.05)	8.0 (3.38)	-0.9 (1.83)
		Median	8.0	0.0	8.0	0.0
		Min, Max	4, 19	-4, 14	4, 17	-7, 7

5 Factor	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
	Week 12	n	75	75	88	88
		Mean (SD)	7.9 (3.60)	-0.2 (1.31)	7.9 (3.23)	-1.0 (1.97)
		Median	8.0	0.0	8.0	-0.5
		Min, Max	4, 20	-4, 4	4, 17	-6, 7
	Week 16	n	71	71	82	82
		Mean (SD)	7.6 (3.34)	-0.3 (1.24)	7.9 (3.31)	-1.1 (2.21)
		Median	7.0	0.0	7.5	0.0
		Min, Max	4, 17	-4, 4	4, 17	-8, 9
	Week 20	n	69	69	78	78
		Mean (SD)	7.8 (3.51)	-0.1 (1.65)	7.9 (3.36)	-1.0 (2.38)
		Median	7.0	0.0	8.0	-0.5
		Min, Max	4, 17	-4, 7	4, 17	-8, 9
	Week 24	n	67	67	72	72
		Mean (SD)	7.6 (3.32)	-0.3 (1.58)	7.9 (3.38)	-1.1 (2.42)
		Median	7.0	0.0	8.0	0.0
		Min, Max	4, 16	-4, 5	4, 17	-8, 9
	Week 28	n	67	67	69	69
		Mean (SD)	7.8 (3.85)	0.0 (2.09)	7.7 (3.36)	-1.2 (2.31)
		Median	7.0	0.0	8.0	-1.0
		Min, Max	4, 20	-4, 11	4, 17	-8, 8
	Week 36	n	63	63	67	67
		Mean (SD)	7.3 (3.29)	-0.4 (1.40)	7.8 (3.52)	-1.0 (2.90)
		Median	7.0	0.0	7.0	-1.0
		Min, Max	4, 16	-4, 3	4, 17	-8, 12
	Week 44	n	60	60	61	61
		Mean (SD)	7.5 (3.36)	-0.2 (1.94)	7.5 (3.40)	-1.2 (2.59)
		Median	7.0	0.0	7.0	-1.0
		Min, Max	4, 16	-7, 5	4, 17	-8, 11
	Week 52	n	57	57	60	60
		Mean (SD)	7.3 (3.27)	-0.4 (1.68)	7.3 (3.65)	-1.3 (3.19)
		Median	6.0	0.0	6.0	-1.0
		Min, Max	4, 16	-8, 4	4, 19	-11, 12

			Cohort 1 (N = 97)		Cohort 2 (N = 103)	
5 Factor	Visit	Statistics	Observed	Change	Observed	Change
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	8.5 (4.27)	0.4 (2.77)	8.4 (4.03)	-0.6 (2.95)
		Median	8.0	0.0	7.0	0.0
		Min, Max	4, 20	-8, 14	4, 20	-11, 12
Anxiety/depression	Baseline	n	97		103	
		Mean (SD)	10.5 (4.05)		11.1 (3.66)	
		Median	10.0		11.0	
		Min, Max	5, 22		5, 23	
	Week 1	n	97	97	103	103
		Mean (SD)	10.3 (3.94)	-0.1 (1.32)	10.9 (3.76)	-0.2 (1.44)
		Median	9.0	0.0	11.0	0.0
		Min, Max	5, 20	-10, 3	5, 24	-4, 7
	Week 2	n	89	89	100	100
		Mean (SD)	10.1 (3.55)	-0.1 (1.71)	10.9 (3.73)	-0.3 (1.80)
		Median	9.0	0.0	11.0	0.0
		Min, Max	5, 19	-10, 7	5, 24	-6, 6
	Week 4	n	87	87	99	99
		Mean (SD)	10.3 (3.80)	0.0 (1.35)	10.6 (3.63)	-0.4 (1.86)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 21	-4, 5	5, 21	-6, 6
	Week 6	n	80	80	95	95
		Mean (SD)	10.2 (3.78)	0.0 (1.37)	10.5 (3.49)	-0.5 (2.06)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 20	-4, 4	5, 22	-6, 6
	Week 8	n	78	78	90	90
		Mean (SD)	10.1 (3.92)	-0.2 (1.79)	10.1 (3.65)	-0.8 (2.39)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 22	-4, 9	5, 23	-7, 7
	Week 12	n	75	75	88	88
		Mean (SD)	9.9 (3.78)	-0.3 (1.60)	10.1 (3.90)	-0.9 (2.65)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 20	-5, 5	5, 23	-7, 6
	Week 16	n	71	71	82	82

5 Factor	Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
		Mean (SD)	9.7 (3.78)	-0.4 (2.06)	10.0 (3.61)	-1.0 (2.83)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 19	-6, 7	5, 23	-9, 5
	Week 20	n	69	69	78	78
		Mean (SD)	9.8 (3.93)	-0.1 (2.21)	9.9 (3.71)	-1.0 (2.76)
		Median	9.0	0.0	9.5	0.0
		Min, Max	5, 22	-6, 7	5, 25	-7, 6
	Week 24	n	67	67	72	72
		Mean (SD)	9.4 (3.68)	-0.5 (2.08)	9.8 (3.87)	-1.3 (3.03)
		Median	8.0	0.0	9.0	0.0
		Min, Max	5, 20	-6, 7	5, 25	-10, 5
	Week 28	n	67	67	69	69
		Mean (SD)	10.0 (4.38)	0.1 (2.81)	9.6 (3.57)	-1.4 (2.96)
		Median	9.0	0.0	10.0	0.0
		Min, Max	5, 29	-6, 12	5, 25	-8, 4
	Week 36	n	63	63	67	67
		Mean (SD)	9.1 (3.08)	-0.6 (1.86)	9.3 (3.17)	-1.7 (3.19)
		Median	9.0	0.0	9.0	-1.0
		Min, Max	5, 18	-7, 4	5, 20	-10, 5
	Week 44	n	60	60	61	61
		Mean (SD)	9.0 (3.09)	-0.6 (2.20)	9.4 (4.08)	-1.4 (3.35)
		Median	8.0	0.0	9.0	-1.0
		Min, Max	5, 20	-8, 4	5, 24	-8, 8
	Week 52	n	57	57	60	60
		Mean (SD)	9.0 (3.08)	-0.5 (2.51)	9.2 (4.09)	-1.6 (3.48)
		Median	8.0	0.0	8.0	-1.0
		Min, Max	5, 20	-9, 6	5, 27	-10, 8
	Week 52 (LOCF)	n	97	97	103	103
		Mean (SD)	10.6 (4.39)	0.1 (2.89)	10.6 (4.32)	-0.5 (3.37)
		Median	10.0	0.0	10.0	0.0
		Min, Max	5, 29	-9, 12	5, 27	-10, 8

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-43　CGI-S スコア変化量（40 試験：ロナセンテープ貼付期）

安全性解析対象集団

Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
Baseline	n	97		103	
	Mean (SD)	3.3 (1.03)		3.4 (1.11)	
	Median	3.0		3.0	
	Min, Max	1, 6		1, 6	
Week 1	n	97	97	103	103
	Mean (SD)	3.2 (1.02)	0.0 (0.30)	3.4 (1.14)	0.0 (0.49)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 6	-1, 1	1, 6	-2, 1
Week 2	n	89	89	100	100
	Mean (SD)	3.2 (0.88)	-0.1 (0.41)	3.3 (1.16)	-0.1 (0.58)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 6	-1, 2	1, 6	-2, 3
Week 4	n	87	87	99	99
	Mean (SD)	3.2 (0.92)	-0.1 (0.35)	3.2 (1.07)	-0.2 (0.49)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 6	-1, 1	1, 6	-2, 1
Week 6	n	80	80	95	95
	Mean (SD)	3.2 (0.95)	-0.1 (0.41)	3.1 (1.07)	-0.3 (0.57)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 6	-1, 2	1, 6	-2, 1
Week 8	n	78	78	90	90
	Mean (SD)	3.2 (0.99)	-0.1 (0.55)	3.1 (1.08)	-0.3 (0.69)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 6	-2, 3	1, 6	-3, 1
Week 12	n	75	75	88	88
	Mean (SD)	3.1 (0.86)	-0.2 (0.43)	3.0 (1.10)	-0.4 (0.80)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 5	-2, 0	1, 6	-3, 3
Week 16	n	71	71	82	82
	Mean (SD)	3.0 (0.84)	-0.2 (0.43)	2.9 (1.05)	-0.4 (0.72)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 5	-2, 0	1, 6	-3, 1
Week 20	n	69	69	78	78
	Mean (SD)	3.0 (0.83)	-0.2 (0.47)	3.0 (1.15)	-0.4 (0.87)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 5	-2, 1	1, 6	-3, 3

Visit	Statistics	Cohort 1 (N = 97) Observed	Change	Cohort 2 (N = 103) Observed	Change
Week 24	n	67	67	72	72
	Mean (SD)	3.0 (0.85)	-0.2 (0.51)	2.9 (1.19)	-0.5 (0.77)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 5	-2, 1	1, 6	-3, 1
Week 28	n	67	67	69	69
	Mean (SD)	3.1 (0.98)	-0.1 (0.62)	2.9 (1.19)	-0.5 (0.78)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 6	-2, 2	1, 6	-3, 1
Week 36	n	63	63	67	67
	Mean (SD)	3.0 (0.83)	-0.2 (0.54)	3.0 (1.19)	-0.4 (0.84)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 5	-2, 1	1, 6	-3, 2
Week 44	n	60	60	61	61
	Mean (SD)	3.0 (0.85)	-0.1 (0.59)	2.9 (1.26)	-0.5 (0.85)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 5	-2, 2	1, 6	-3, 1
Week 52	n	57	57	60	60
	Mean (SD)	3.0 (0.83)	-0.1 (0.65)	2.8 (1.18)	-0.6 (0.83)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 5	-2, 1	1, 6	-3, 1
Week 52 (LOCF)	n	97	97	103	103
	Mean (SD)	3.3 (1.07)	0.0 (0.76)	3.2 (1.30)	-0.2 (1.03)
	Median	3.0	0.0	3.0	0.0
	Min, Max	1, 6	-2, 3	1, 6	-3, 3

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-44　PANSS サブスケール別合計スコア変化量
（40 試験：コホート 1、ロナセン錠投与期）

ロナセン錠投与集団

Subscale	Visit	Statistics	Cohort 1 (N = 108) Observed	Change
Positive subscale	Tab-Baseline	n	108	
		Mean (SD)	14.2 (5.63)	
		Median	14.0	
		Min, Max	7, 30	
	Tab-Week 1	n	106	106
		Mean (SD)	14.2 (5.81)	-0.2 (1.58)

Subscale	Visit	Statistics	Cohort 1 (N = 108) Observed	Change
		Median	13.5	0.0
		Min, Max	7, 30	-5, 9
	Tab-Week 2	n	101	101
		Mean (SD)	13.8 (5.50)	-0.6 (1.36)
		Median	13.0	0.0
		Min, Max	7, 30	-5, 2
	Tab-Week 4	n	99	99
		Mean (SD)	13.6 (5.50)	-0.8 (1.61)
		Median	13.0	0.0
		Min, Max	7, 30	-6, 2
	Tab-Week 6	n	97	97
		Mean (SD)	13.4 (5.46)	-1.1 (2.02)
		Median	13.0	0.0
		Min, Max	7, 30	-10, 3
Negative subscale	Tab-Baseline	n	108	
		Mean (SD)	17.9 (7.27)	
		Median	18.0	
		Min, Max	7, 41	
	Tab-Week 1	n	106	106
		Mean (SD)	18.1 (7.41)	0.2 (1.90)
		Median	18.5	0.0
		Min, Max	7, 41	-4, 13
	Tab-Week 2	n	101	101
		Mean (SD)	17.9 (7.20)	-0.1 (1.76)
		Median	18.0	0.0
		Min, Max	7, 41	-6, 13
	Tab-Week 4	n	99	99
		Mean (SD)	17.8 (6.87)	-0.2 (1.89)
		Median	18.0	0.0
		Min, Max	7, 38	-6, 9
	Tab-Week 6	n	97	97
		Mean (SD)	17.5 (6.95)	-0.5 (2.51)
		Median	17.0	0.0

Subscale	Visit	Statistics	Cohort 1 (N = 108) Observed	Change
		Min, Max	7, 38	-7, 15
General psychopathology subscale	Tab-Baseline	n	108	
		Mean (SD)	33.6 (11.42)	
		Median	33.0	
		Min, Max	17, 69	
	Tab-Week 1	n	106	106
		Mean (SD)	34.0 (11.74)	0.2 (3.38)
		Median	33.5	0.0
		Min, Max	16, 68	-7, 22
	Tab-Week 2	n	101	101
		Mean (SD)	33.3 (11.56)	-0.7 (3.50)
		Median	33.0	0.0
		Min, Max	16, 67	-9, 28
	Tab-Week 4	n	99	99
		Mean (SD)	33.2 (11.19)	-0.9 (2.79)
		Median	34.0	0.0
		Min, Max	16, 66	-10, 12
	Tab-Week 6	n	97	97
		Mean (SD)	32.7 (11.13)	-1.3 (3.95)
		Median	33.0	0.0
		Min, Max	16, 66	-12, 25

Summary statistics for the observed value and change from Tab-baseline value (denoted by change) are based on subjects with both a baseline of the DSP-5423 (tablet) treatment phase and the target visit observation.

表 2.7.3.6-45　PANSS 5 因子モデル別合計スコア変化量
(40 試験：コホート 1、ロナセン錠投与期)

ロナセン錠投与集団

5 Factor	Visit	Statistics	Cohort 1 (N = 108) Observed	Change
Negative symptoms	Tab-Baseline	n	108	
		Mean (SD)	15.6 (6.40)	
		Median	15.0	
		Min, Max	6, 35	
	Tab-Week 1	n	106	106

5 Factor	Visit	Statistics	Cohort 1 (N = 108) Observed	Change
		Mean (SD)	15.8 (6.61)	0.2 (1.99)
		Median	15.0	0.0
		Min, Max	6, 35	-4, 13
	Tab-Week 2	n	101	101
		Mean (SD)	15.6 (6.43)	-0.1 (1.53)
		Median	15.0	0.0
		Min, Max	6, 35	-3, 11
	Tab-Week 4	n	99	99
		Mean (SD)	15.5 (6.06)	-0.2 (1.79)
		Median	15.0	0.0
		Min, Max	6, 32	-5, 9
	Tab-Week 6	n	97	97
		Mean (SD)	15.2 (6.05)	-0.4 (2.34)
		Median	15.0	0.0
		Min, Max	6, 32	-8, 13
Excitement	Tab-Baseline	n	108	
		Mean (SD)	7.0 (2.75)	
		Median	6.5	
		Min, Max	4, 16	
	Tab-Week 1	n	106	106
		Mean (SD)	7.0 (2.80)	0.0 (0.86)
		Median	7.0	0.0
		Min, Max	4, 17	-2, 4
	Tab-Week 2	n	101	101
		Mean (SD)	6.9 (2.71)	-0.1 (0.78)
		Median	6.0	0.0
		Min, Max	4, 17	-2, 5
	Tab-Week 4	n	99	99
		Mean (SD)	6.7 (2.74)	-0.3 (0.83)
		Median	6.0	0.0
		Min, Max	4, 17	-3, 3
	Tab-Week 6	n	97	97
		Mean (SD)	6.6 (2.56)	-0.4 (0.98)

5 Factor	Visit	Statistics	Cohort 1 (N = 108) Observed	Change
		Median	6.0	0.0
		Min, Max	4, 14	-4, 3
Cognitive disorders	Tab-Baseline	n	108	
		Mean (SD)	10.4 (3.98)	
		Median	10.0	
		Min, Max	5, 21	
	Tab-Week 1	n	106	106
		Mean (SD)	10.5 (4.19)	0.1 (1.07)
		Median	10.0	0.0
		Min, Max	5, 21	-2, 9
	Tab-Week 2	n	101	101
		Mean (SD)	10.4 (3.94)	-0.1 (1.06)
		Median	10.0	0.0
		Min, Max	5, 21	-4, 7
	Tab-Week 4	n	99	99
		Mean (SD)	10.4 (3.93)	-0.2 (0.98)
		Median	11.0	0.0
		Min, Max	5, 20	-4, 3
	Tab-Week 6	n	97	97
		Mean (SD)	10.2 (3.95)	-0.3 (1.04)
		Median	10.0	0.0
		Min, Max	5, 20	-4, 4
Positive symptoms	Tab-Baseline	n	108	
		Mean (SD)	8.6 (3.82)	
		Median	8.0	
		Min, Max	4, 19	
	Tab-Week 1	n	106	106
		Mean (SD)	8.6 (3.78)	-0.1 (1.04)
		Median	8.0	0.0
		Min, Max	4, 19	-4, 5
	Tab-Week 2	n	101	101
		Mean (SD)	8.4 (3.61)	-0.3 (1.08)
		Median	8.0	0.0

5 Factor	Visit	Statistics	Cohort 1 (N = 108) Observed	Change
		Min, Max	4, 19	-5, 3
	Tab-Week 4	n	99	99
		Mean (SD)	8.3 (3.62)	-0.5 (1.02)
		Median	8.0	0.0
		Min, Max	4, 19	-4, 2
	Tab-Week 6	n	97	97
		Mean (SD)	8.2 (3.66)	-0.6 (1.27)
		Median	8.0	0.0
		Min, Max	4, 19	-5, 3
Anxiety/depression	Tab-Baseline	n	108	
		Mean (SD)	11.0 (4.28)	
		Median	10.0	
		Min, Max	5, 28	
	Tab-Week 1	n	106	106
		Mean (SD)	11.1 (4.41)	0.0 (1.69)
		Median	10.0	0.0
		Min, Max	5, 28	-6, 9
	Tab-Week 2	n	101	101
		Mean (SD)	10.7 (4.33)	-0.5 (1.75)
		Median	10.0	0.0
		Min, Max	5, 28	-8, 7
	Tab-Week 4	n	99	99
		Mean (SD)	10.6 (4.15)	-0.6 (1.61)
		Median	10.0	0.0
		Min, Max	5, 23	-8, 3
	Tab-Week 6	n	97	97
		Mean (SD)	10.5 (4.05)	-0.8 (1.95)
		Median	10.0	0.0
		Min, Max	5, 22	-8, 7

Summary statistics for the observed value and change from Tab-baseline value (denoted by change) are based on subjects with both a baseline of the DSP-5423 (tablet) treatment phase and the target visit observation.

表 2.7.3.6-46　CGI-S スコア変化量（40 試験：コホート 1、ロナセン錠投与期）

ロナセン錠投与集団

Visit	Statistics	Cohort 1 (N = 108) Observed	Change
Tab-Baseline	n	108	
	Mean (SD)	3.4 (1.06)	
	Median	3.0	
	Min, Max	1, 6	
Tab-Week 1	n	106	106
	Mean (SD)	3.4 (1.11)	0.0 (0.48)
	Median	3.0	0.0
	Min, Max	1, 6	-1, 3
Tab-Week 2	n	101	101
	Mean (SD)	3.3 (1.07)	-0.1 (0.32)
	Median	3.0	0.0
	Min, Max	1, 6	-1, 1
Tab-Week 4	n	99	99
	Mean (SD)	3.4 (1.04)	-0.1 (0.33)
	Median	3.0	0.0
	Min, Max	1, 6	-1, 1
Tab-Week 6	n	97	97
	Mean (SD)	3.3 (1.03)	-0.2 (0.43)
	Median	3.0	0.0
	Min, Max	1, 6	-2, 0

Summary statistics for the observed value and change from Tab-baseline value (denoted by change) are based on subjects with both a baseline of the DSP-5423 (tablet) treatment phase and the target visit observation.

表 2.7.3.6-47　PANSS 合計スコア変化量（40 試験：ロナセンテープ貼付期：性別）

安全性解析対象集団

Sex Male		Cohort 1 (N = 43)		Cohort 2 (N = 48)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	43		48	
	Mean (SD)	65.1 (20.20)		67.5 (20.45)	
	Median	64.0		68.5	
	Min, Max	31, 119		30, 119	
Week 1	n	43	43	48	48
	Mean (SD)	64.3 (20.16)	-0.8 (2.94)	66.9 (20.64)	-0.7 (3.49)
	Median	64.0	0.0	68.0	0.0
	Min, Max	31, 116	-8, 9	30, 121	-9, 9

Sex Male		Cohort 1 (N = 43)		Cohort 2 (N = 48)	
Visit	Statistics	Observed	Change	Observed	Change
Week 2	n	37	37	47	47
	Mean (SD)	62.9 (17.18)	-1.1 (6.37)	67.1 (20.62)	-1.1 (6.69)
	Median	63.0	0.0	67.0	-1.0
	Min, Max	37, 100	-18, 26	30, 125	-15, 33
Week 4	n	35	35	47	47
	Mean (SD)	63.3 (17.07)	-1.3 (3.04)	65.7 (21.42)	-2.0 (6.31)
	Median	60.0	0.0	66.0	0.0
	Min, Max	38, 100	-9, 4	30, 134	-17, 15
Week 6	n	34	34	44	44
	Mean (SD)	63.6 (16.94)	-0.6 (5.64)	64.1 (18.52)	-2.3 (6.06)
	Median	61.5	-0.5	68.0	0.0
	Min, Max	38, 95	-10, 27	30, 103	-16, 16
Week 8	n	33	33	40	40
	Mean (SD)	62.6 (18.41)	-1.9 (5.22)	62.3 (20.00)	-4.0 (8.45)
	Median	60.0	0.0	62.5	-1.0
	Min, Max	37, 102	-19, 10	30, 107	-31, 18
Week 12	n	33	33	40	40
	Mean (SD)	62.2 (18.71)	-2.4 (5.66)	61.8 (19.95)	-4.5 (9.77)
	Median	60.0	-1.0	60.5	-2.0
	Min, Max	36, 100	-18, 9	30, 105	-33, 20
Week 16	n	32	32	37	37
	Mean (SD)	59.9 (17.24)	-3.5 (5.91)	61.9 (19.49)	-5.2 (10.39)
	Median	57.0	-1.0	61.0	-2.0
	Min, Max	36, 95	-17, 10	30, 108	-37, 19
Week 20	n	32	32	34	34
	Mean (SD)	61.3 (18.07)	-2.1 (6.21)	61.2 (19.22)	-4.5 (10.55)
	Median	59.0	0.0	60.0	-2.0
	Min, Max	34, 99	-15, 14	30, 104	-35, 23
Week 24	n	32	32	31	31
	Mean (SD)	59.7 (17.29)	-3.7 (6.11)	59.7 (20.18)	-6.9 (11.62)
	Median	57.5	-1.0	60.0	-1.0
	Min, Max	34, 97	-17, 5	30, 103	-38, 8
Week 28	n	32	32	30	30

Sex Male		Cohort 1 (N = 43)		Cohort 2 (N = 48)	
Visit	Statistics	Observed	Change	Observed	Change
	Mean (SD)	62.7 (21.88)	-0.7 (12.58)	59.7 (20.07)	-6.7 (10.84)
	Median	59.5	0.0	59.0	-1.5
	Min, Max	34, 128	-23, 53	30, 103	-38, 11
Week 36	n	30	30	30	30
	Mean (SD)	58.8 (16.85)	-3.3 (7.25)	59.5 (19.29)	-6.9 (13.23)
	Median	56.0	0.0	60.0	-1.5
	Min, Max	34, 95	-18, 10	30, 103	-38, 23
Week 44	n	27	27	27	27
	Mean (SD)	59.1 (17.74)	-1.9 (7.75)	58.2 (19.32)	-8.1 (11.79)
	Median	56.0	0.0	59.0	-4.0
	Min, Max	34, 94	-17, 16	30, 103	-38, 11
Week 52	n	26	26	27	27
	Mean (SD)	58.2 (17.36)	-3.0 (5.79)	57.3 (19.11)	-9.0 (12.70)
	Median	55.5	-1.0	59.0	-4.0
	Min, Max	33, 93	-18, 8	30, 103	-48, 8
Week 52 (LOCF)	n	43	43	48	48
	Mean (SD)	65.7 (23.03)	0.7 (11.98)	65.6 (22.87)	-1.9 (14.44)
	Median	64.0	0.0	64.0	0.0
	Min, Max	31, 128	-18, 53	30, 134	-48, 33

Sex Female		Cohort 1 (N = 54)		Cohort 2 (N = 55)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	54		55	
	Mean (SD)	62.4 (22.12)		67.5 (22.27)	
	Median	59.0		67.0	
	Min, Max	30, 103		30, 114	
Week 1	n	54	54	55	55
	Mean (SD)	62.2 (22.15)	-0.2 (3.32)	66.2 (21.49)	-1.2 (4.83)
	Median	60.5	0.0	65.0	0.0
	Min, Max	30, 109	-16, 8	30, 111	-20, 10
Week 2	n	52	52	53	53
	Mean (SD)	61.6 (21.91)	-0.3 (4.19)	65.7 (21.70)	-1.9 (5.26)
	Median	57.5	0.0	66.0	-1.0
	Min, Max	30, 109	-22, 7	30, 108	-22, 16

Sex Female		Cohort 1 (N = 54)		Cohort 2 (N = 55)	
Visit	Statistics	Observed	Change	Observed	Change
Week 4	n	52	52	52	52
	Mean (SD)	62.0 (22.05)	-0.6 (4.20)	63.7 (21.42)	-3.1 (7.14)
	Median	57.5	0.0	65.5	-1.5
	Min, Max	30, 116	-18, 14	30, 118	-30, 8
Week 6	n	46	46	51	51
	Mean (SD)	62.3 (23.15)	-0.5 (5.30)	62.7 (21.21)	-4.2 (7.98)
	Median	60.0	0.0	63.0	-3.0
	Min, Max	30, 127	-15, 25	30, 108	-32, 14
Week 8	n	45	45	50	50
	Mean (SD)	62.0 (23.72)	-0.1 (9.49)	61.9 (21.26)	-5.1 (9.45)
	Median	59.0	0.0	61.0	-2.5
	Min, Max	30, 123	-13, 46	30, 112	-35, 14
Week 12	n	42	42	48	48
	Mean (SD)	60.3 (22.47)	-1.5 (6.16)	61.6 (21.82)	-5.3 (11.03)
	Median	57.0	0.0	61.0	-3.0
	Min, Max	30, 115	-14, 15	30, 114	-41, 33
Week 16	n	39	39	45	45
	Mean (SD)	58.1 (21.74)	-2.3 (6.16)	61.1 (21.85)	-6.9 (10.91)
	Median	54.0	-1.0	60.0	-3.0
	Min, Max	30, 109	-16, 11	30, 114	-36, 12
Week 20	n	37	37	44	44
	Mean (SD)	57.8 (22.22)	-2.0 (6.53)	61.2 (22.23)	-6.8 (11.81)
	Median	51.0	-1.0	55.5	-2.5
	Min, Max	30, 105	-17, 13	30, 116	-41, 17
Week 24	n	35	35	41	41
	Mean (SD)	57.3 (22.35)	-2.5 (6.97)	62.0 (23.17)	-7.6 (13.49)
	Median	54.0	0.0	57.0	-3.0
	Min, Max	30, 103	-18, 13	30, 122	-43, 16
Week 28	n	35	35	39	39
	Mean (SD)	58.1 (22.58)	-1.7 (7.79)	59.8 (21.44)	-8.7 (13.75)
	Median	54.0	-1.0	56.0	-3.0
	Min, Max	30, 108	-17, 18	30, 105	-45, 8

Sex Female		Cohort 1 (N = 54)		Cohort 2 (N = 55)	
Visit	Statistics	Observed	Change	Observed	Change
Week 36	n	33	33	37	37
	Mean (SD)	55.1 (20.16)	-3.6 (7.35)	59.1 (22.73)	-8.7 (14.95)
	Median	51.0	-1.0	52.0	-3.0
	Min, Max	30, 99	-22, 7	30, 105	-46, 23
Week 44	n	33	33	34	34
	Mean (SD)	55.2 (21.64)	-3.4 (9.06)	58.9 (23.84)	-8.0 (15.47)
	Median	50.0	-1.0	48.0	-3.0
	Min, Max	30, 110	-29, 14	30, 117	-43, 26
Week 52	n	31	31	33	33
	Mean (SD)	54.3 (20.39)	-4.0 (10.18)	56.8 (23.71)	-9.4 (16.97)
	Median	49.0	-1.0	47.0	-4.0
	Min, Max	30, 112	-37, 12	30, 117	-44, 37
Week 52 (LOCF)	n	54	54	55	55
	Mean (SD)	61.7 (23.00)	-0.7 (11.35)	62.7 (24.68)	-4.8 (16.02)
	Median	57.5	0.0	60.0	-2.0
	Min, Max	30, 112	-37, 46	30, 122	-44, 37

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-48　PANSS 合計スコア変化量（40 試験：ロナセンテープ貼付期：年齢）

安全性解析対象集団

Age (years) <65		Cohort 1 (N = 87)		Cohort 2 (N = 94)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	87		94	
	Mean (SD)	62.7 (20.87)		65.9 (20.80)	
	Median	63.0		67.5	
	Min, Max	30, 119		30, 119	
Week 1	n	87	87	94	94
	Mean (SD)	62.2 (20.88)	-0.5 (3.32)	64.9 (20.35)	-1.0 (4.41)
	Median	63.0	0.0	66.0	0.0
	Min, Max	30, 116	-16, 9	30, 121	-20, 10
Week 2	n	79	79	91	91
	Mean (SD)	61.0 (19.38)	-0.7 (5.48)	64.8 (20.51)	-1.5 (6.18)
	Median	60.0	0.0	66.0	-1.0
	Min, Max	30, 109	-22, 26	30, 125	-22, 33

Age (years) <65		Cohort 1 (N = 87)		Cohort 2 (N = 94)	
Visit	Statistics	Observed	Change	Observed	Change
Week 4	n	77	77	91	91
	Mean (SD)	61.4 (19.57)	-0.9 (3.96)	63.3 (20.99)	-2.7 (6.91)
	Median	58.0	0.0	65.0	0.0
	Min, Max	30, 116	-18, 14	30, 134	-30, 15
Week 6	n	71	71	88	88
	Mean (SD)	61.7 (20.28)	-0.4 (5.67)	62.1 (19.33)	-3.3 (7.28)
	Median	60.0	0.0	63.5	-1.0
	Min, Max	30, 127	-15, 27	30, 108	-32, 16
Week 8	n	69	69	83	83
	Mean (SD)	61.0 (21.21)	-0.7 (8.41)	60.7 (19.91)	-4.6 (9.14)
	Median	58.0	0.0	61.0	-2.0
	Min, Max	30, 123	-19, 46	30, 112	-35, 18
Week 12	n	68	68	81	81
	Mean (SD)	60.1 (20.38)	-1.7 (5.99)	60.3 (20.30)	-4.9 (10.71)
	Median	57.0	0.0	60.0	-2.0
	Min, Max	30, 115	-18, 15	30, 114	-41, 33
Week 16	n	65	65	75	75
	Mean (SD)	58.3 (19.58)	-2.6 (6.01)	59.9 (20.10)	-6.3 (10.96)
	Median	56.0	-1.0	60.0	-2.0
	Min, Max	30, 109	-17, 11	30, 114	-37, 19
Week 20	n	63	63	72	72
	Mean (SD)	59.0 (20.41)	-1.5 (6.15)	59.8 (20.17)	-6.0 (11.64)
	Median	56.0	0.0	59.5	-2.0
	Min, Max	30, 105	-15, 14	30, 116	-41, 23
Week 24	n	61	61	67	67
	Mean (SD)	58.0 (20.02)	-2.6 (6.37)	59.0 (20.90)	-7.8 (12.84)
	Median	56.0	0.0	57.0	-2.0
	Min, Max	30, 103	-18, 13	30, 122	-43, 16
Week 28	n	61	61	65	65
	Mean (SD)	60.1 (22.49)	-0.5 (10.34)	58.0 (19.60)	-8.1 (12.79)
	Median	56.0	0.0	56.0	-2.0
	Min, Max	30, 128	-23, 53	30, 99	-45, 11

Age (years) <65		Cohort 1 (N = 87)		Cohort 2 (N = 94)	
Visit	Statistics	Observed	Change	Observed	Change
Week 36	n	57	57	64	64
	Mean (SD)	56.3 (18.41)	-2.9 (7.04)	57.8 (20.00)	-8.2 (14.37)
	Median	54.0	0.0	53.5	-3.0
	Min, Max	30, 99	-22, 10	30, 100	-46, 23
Week 44	n	54	54	58	58
	Mean (SD)	56.5 (19.87)	-1.9 (8.14)	56.9 (20.63)	-8.4 (14.13)
	Median	52.0	0.0	52.0	-4.0
	Min, Max	30, 110	-29, 16	30, 117	-43, 26
Week 52	n	51	51	57	57
	Mean (SD)	55.5 (18.85)	-2.7 (8.05)	55.2 (20.20)	-9.7 (15.33)
	Median	55.0	-1.0	49.0	-4.0
	Min, Max	30, 112	-37, 12	30, 117	-48, 37
Week 52 (LOCF)	n	87	87	94	94
	Mean (SD)	63.3 (22.98)	0.6 (11.72)	62.4 (23.53)	-3.6 (15.88)
	Median	61.0	0.0	60.0	-1.5
	Min, Max	30, 128	-37, 53	30, 134	-48, 37

Age (years) >=65		Cohort 1 (N = 10)		Cohort 2 (N = 9)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	10		9	
	Mean (SD)	71.3 (23.84)		83.9 (21.10)	
	Median	77.0		89.0	
	Min, Max	37, 100		49, 108	
Week 1	n	10	10	9	9
	Mean (SD)	71.1 (23.55)	-0.2 (0.92)	83.3 (21.48)	-0.6 (1.88)
	Median	76.0	0.0	87.0	0.0
	Min, Max	37, 100	-1, 2	49, 107	-4, 3
Week 2	n	10	10	9	9
	Mean (SD)	71.1 (23.47)	-0.2 (1.55)	82.6 (21.34)	-1.3 (3.24)
	Median	75.0	0.0	85.0	0.0
	Min, Max	37, 100	-3, 3	49, 107	-9, 1
Week 4	n	10	10	8	8
	Mean (SD)	70.9 (23.16)	-0.4 (1.71)	79.5 (20.74)	-1.4 (4.60)
	Median	74.5	-0.5	76.5	0.0

Age (years) >=65		Cohort 1 (N = 10)		Cohort 2 (N = 9)	
Visit	Statistics	Observed	Change	Observed	Change
	Min, Max	37, 100	-4, 2	51, 107	-12, 2
Week 6	n	9	9	7	7
	Mean (SD)	72.4 (22.07)	-2.1 (2.26)	79.3 (21.85)	-3.9 (6.28)
	Median	75.0	-2.0	76.0	-1.0
	Min, Max	37, 96	-5, 1	50, 107	-13, 1
Week 8	n	9	9	7	7
	Mean (SD)	72.0 (22.55)	-2.6 (2.55)	78.4 (23.17)	-4.7 (7.52)
	Median	73.0	-2.0	72.0	-1.0
	Min, Max	37, 96	-7, 0	47, 107	-17, 2
Week 12	n	7	7	7	7
	Mean (SD)	71.1 (23.67)	-3.9 (5.18)	78.0 (22.09)	-5.1 (6.67)
	Median	67.0	-2.0	73.0	-3.0
	Min, Max	37, 100	-14, 0	49, 106	-16, 1
Week 16	n	6	6	7	7
	Mean (SD)	65.5 (22.04)	-5.3 (6.25)	78.3 (21.00)	-4.9 (6.77)
	Median	64.5	-3.5	76.0	-1.0
	Min, Max	37, 96	-16, 0	49, 106	-13, 2
Week 20	n	6	6	6	6
	Mean (SD)	63.5 (20.94)	-7.3 (6.41)	78.5 (22.84)	-3.7 (5.01)
	Median	62.0	-5.5	74.0	-1.5
	Min, Max	37, 93	-17, 0	49, 105	-10, 1
Week 24	n	6	6	5	5
	Mean (SD)	62.8 (20.88)	-8.0 (6.96)	88.4 (15.29)	-0.4 (7.02)
	Median	60.5	-6.0	83.0	0.0
	Min, Max	37, 93	-17, 0	69, 105	-11, 8
Week 28	n	6	6	4	4
	Mean (SD)	62.7 (20.69)	-8.2 (7.11)	88.5 (18.81)	-3.8 (6.24)
	Median	60.5	-7.0	91.5	-1.0
	Min, Max	38, 93	-17, 1	66, 105	-13, 0
Week 36	n	6	6	3	3
	Mean (SD)	61.8 (21.49)	-9.0 (7.46)	91.3 (21.96)	-0.7 (1.15)
	Median	59.5	-8.0	103.0	0.0
	Min, Max	37, 93	-20, 0	66, 105	-2, 0

Age (years) >=65		Cohort 1 (N = 10)		Cohort 2 (N = 9)	
Visit	Statistics	Observed	Change	Observed	Change
Week 44	n	6	6	3	3
	Mean (SD)	61.0 (21.69)	-9.8 (8.68)	90.3 (22.81)	-1.7 (1.53)
	Median	57.0	-8.0	103.0	-2.0
	Min, Max	37, 93	-23, 0	64, 104	-3, 0
Week 52	n	6	6	3	3
	Mean (SD)	60.2 (21.66)	-10.7 (8.76)	91.7 (20.50)	-0.3 (2.52)
	Median	56.5	-9.5	103.0	0.0
	Min, Max	37, 92	-24, 0	68, 104	-3, 2
Week 52 (LOCF)	n	10	10	9	9
	Mean (SD)	65.0 (24.22)	-6.3 (8.65)	81.9 (19.69)	-2.0 (6.93)
	Median	56.5	-2.5	80.0	0.0
	Min, Max	37, 100	-24, 2	49, 107	-13, 8

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-49　PANSS 合計スコア変化量

（40 試験：ロナセンテープ貼付期、抗精神病薬の前治療薬使用の有無）

安全性解析対象集団

Prior Antipsychotics Status Yes		Cohort 1 (N = 96)		Cohort 2 (N = 101)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	96		101	
	Mean (SD)	63.5 (21.32)		67.0 (21.16)	
	Median	63.5		68.0	
	Min, Max	30, 119		30, 119	
Week 1	n	96	96	101	101
	Mean (SD)	63.0 (21.30)	-0.5 (3.17)	66.0 (20.78)	-1.0 (4.28)
	Median	63.0	0.0	66.0	0.0
	Min, Max	30, 116	-16, 9	30, 121	-20, 10
Week 2	n	88	88	98	98
	Mean (SD)	62.0 (20.07)	-0.6 (5.22)	65.8 (20.86)	-1.6 (5.98)
	Median	61.0	0.0	66.0	-1.0
	Min, Max	30, 109	-22, 26	30, 125	-22, 33

Prior Antipsychotics Status Yes		Cohort 1 (N = 96)		Cohort 2 (N = 101)	
Visit	Statistics	Observed	Change	Observed	Change
Week 4	n	86	86	97	97
	Mean (SD)	62.4 (20.18)	-0.9 (3.79)	64.0 (20.99)	-2.7 (6.69)
	Median	58.0	0.0	65.0	0.0
	Min, Max	30, 116	-18, 14	30, 134	-30, 15
Week 6	n	79	79	94	94
	Mean (SD)	62.8 (20.73)	-0.6 (5.44)	62.9 (19.50)	-3.4 (7.21)
	Median	61.0	0.0	64.0	-1.0
	Min, Max	30, 127	-15, 27	30, 108	-32, 16
Week 8	n	77	77	89	89
	Mean (SD)	62.1 (21.61)	-0.9 (8.02)	61.6 (20.15)	-4.7 (9.02)
	Median	59.0	0.0	62.0	-2.0
	Min, Max	30, 123	-19, 46	30, 112	-35, 18
Week 12	n	74	74	87	87
	Mean (SD)	60.9 (20.87)	-1.9 (5.95)	61.2 (20.44)	-5.0 (10.47)
	Median	57.0	-0.5	61.0	-2.0
	Min, Max	30, 115	-18, 15	30, 114	-41, 33
Week 16	n	70	70	81	81
	Mean (SD)	58.7 (19.77)	-2.9 (6.05)	60.9 (20.21)	-6.2 (10.70)
	Median	56.5	-1.0	60.0	-2.0
	Min, Max	30, 109	-17, 11	30, 114	-37, 19
Week 20	n	68	68	77	77
	Mean (SD)	59.2 (20.37)	-2.1 (6.34)	60.6 (20.36)	-5.9 (11.33)
	Median	56.5	0.0	60.0	-2.0
	Min, Max	30, 105	-17, 14	30, 116	-41, 23
Week 24	n	67	67	71	71
	Mean (SD)	58.4 (19.98)	-3.1 (6.55)	60.4 (21.32)	-7.4 (12.71)
	Median	56.0	-1.0	59.0	-2.0
	Min, Max	30, 103	-18, 13	30, 122	-43, 16
Week 28	n	67	67	68	68
	Mean (SD)	60.3 (22.20)	-1.2 (10.29)	59.1 (20.10)	-7.9 (12.59)
	Median	56.0	-1.0	56.0	-2.0
	Min, Max	30, 128	-23, 53	30, 103	-45, 11

Prior Antipsychotics Status Yes		Cohort 1 (N = 96)		Cohort 2 (N = 101)	
Visit	Statistics	Observed	Change	Observed	Change
Week 36	n	63	63	66	66
	Mean (SD)	56.8 (18.60)	-3.5 (7.25)	58.6 (20.49)	-8.0 (14.22)
	Median	54.0	-1.0	56.0	-2.5
	Min, Max	30, 99	-22, 10	30, 103	-46, 23
Week 44	n	60	60	60	60
	Mean (SD)	57.0 (19.91)	-2.7 (8.46)	57.8 (21.14)	-8.2 (13.95)
	Median	52.5	-1.0	55.5	-3.5
	Min, Max	30, 110	-29, 16	30, 117	-43, 26
Week 52	n	57	57	59	59
	Mean (SD)	56.0 (19.00)	-3.5 (8.41)	56.2 (20.86)	-9.3 (15.19)
	Median	55.0	-1.0	50.0	-4.0
	Min, Max	30, 112	-37, 12	30, 117	-48, 37
Week 52 (LOCF)	n	96	96	101	101
	Mean (SD)	63.3 (23.06)	-0.2 (11.65)	63.5 (23.58)	-3.6 (15.39)
	Median	60.5	0.0	63.0	-1.0
	Min, Max	30, 128	-37, 53	30, 134	-48, 37

Prior Antipsychotics Status No		Cohort 1 (N = 1)		Cohort 2 (N = 2)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	1		2	
	Mean (SD)	73.0 (.)		91.5 (21.92)	
	Median	73.0		91.5	
	Min, Max	73, 73		76, 107	
Week 1	n	1	1	2	2
	Mean (SD)	72.0 (.)	-1.0 (.)	92.5 (20.51)	1.0 (1.41)
	Median	72.0	-1.0	92.5	1.0
	Min, Max	72, 72	-1, -1	78, 107	0, 2
Week 2	n	1	1	2	2
	Mean (SD)	73.0 (.)	0.0 (.)	94.0 (18.38)	2.5 (3.54)
	Median	73.0	0.0	94.0	2.5
	Min, Max	73, 73	0, 0	81, 107	0, 5

Prior Antipsychotics Status No		Cohort 1 (N = 1)		Cohort 2 (N = 2)	
Visit	Statistics	Observed	Change	Observed	Change
Week 4	n	1	1	2	2
	Mean (SD)	73.0 (.)	0.0 (.)	96.5 (14.85)	5.0 (7.07)
	Median	73.0	0.0	96.5	5.0
	Min, Max	73, 73	0, 0	86, 107	0, 10
Week 6	n	1	1	1	1
	Mean (SD)	73.0 (.)	0.0 (.)	107.0 (.)	0.0 (.)
	Median	73.0	0.0	107.0	0.0
	Min, Max	73, 73	0, 0	107, 107	0, 0
Week 8	n	1	1	1	1
	Mean (SD)	74.0 (.)	1.0 (.)	107.0 (.)	0.0 (.)
	Median	74.0	1.0	107.0	0.0
	Min, Max	74, 74	1, 1	107, 107	0, 0
Week 12	n	1	1	1	1
	Mean (SD)	74.0 (.)	1.0 (.)	106.0 (.)	-1.0 (.)
	Median	74.0	1.0	106.0	-1.0
	Min, Max	74, 74	1, 1	106, 106	-1, -1
Week 16	n	1	1	1	1
	Mean (SD)	75.0 (.)	2.0 (.)	106.0 (.)	-1.0 (.)
	Median	75.0	2.0	106.0	-1.0
	Min, Max	75, 75	2, 2	106, 106	-1, -1
Week 20	n	1	1	1	1
	Mean (SD)	77.0 (.)	4.0 (.)	105.0 (.)	-2.0 (.)
	Median	77.0	4.0	105.0	-2.0
	Min, Max	77, 77	4, 4	105, 105	-2, -2
Week 24	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	105.0 (.)	-2.0 (.)
	Median	.	.	105.0	-2.0
	Min, Max	., .	., .	105, 105	-2, -2
Week 28	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	105.0 (.)	-2.0 (.)
	Median	.	.	105.0	-2.0
	Min, Max	., .	., .	105, 105	-2, -2

Prior Antipsychotics Status No		Cohort 1 (N = 1)		Cohort 2 (N = 2)	
Visit	Statistics	Observed	Change	Observed	Change
Week 36	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	105.0 (.)	-2.0 (.)
	Median	.	.	105.0	-2.0
	Min, Max	., .	., .	105, 105	-2, -2
Week 44	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	104.0 (.)	-3.0 (.)
	Median	.	.	104.0	-3.0
	Min, Max	., .	., .	104, 104	-3, -3
Week 52	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	104.0 (.)	-3.0 (.)
	Median	.	.	104.0	-3.0
	Min, Max	., .	., .	104, 104	-3, -3
Week 52 (LOCF)	n	1	1	2	2
	Mean (SD)	77.0 (.)	4.0 (.)	95.0 (12.73)	3.5 (9.19)
	Median	77.0	4.0	95.0	3.5
	Min, Max	77, 77	4, 4	86, 104	-3, 10

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-50　PANSS 合計スコア変化量
（40 試験：ロナセンテープ貼付期、罹病期間別）

安全性解析対象集団

Duration of illness (years) <5		Cohort 1 (N = 20)		Cohort 2 (N = 15)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	20		15	
	Mean (SD)	62.5 (20.75)		65.4 (18.44)	
	Median	58.0		67.0	
	Min, Max	30, 103		30, 90	
Week 1	n	20	20	15	15
	Mean (SD)	61.2 (20.43)	-1.3 (4.91)	61.4 (15.63)	-4.0 (5.30)
	Median	60.0	0.0	64.0	-3.0
	Min, Max	31, 109	-16, 8	30, 80	-20, 0
Week 2	n	19	19	15	15

Duration of illness (years) <5		Cohort 1 (N = 20)		Cohort 2 (N = 15)	
Visit	Statistics	Observed	Change	Observed	Change
	Mean (SD)	61.4 (18.64)	-2.7 (6.92)	61.3 (15.22)	-4.1 (6.13)
	Median	57.0	-1.0	63.0	-3.0
	Min, Max	34, 98	-22, 7	30, 79	-22, 4
Week 4	n	18	18	15	15
	Mean (SD)	63.9 (17.62)	-2.1 (4.99)	59.5 (13.73)	-5.9 (7.89)
	Median	58.5	-0.5	64.0	-3.0
	Min, Max	40, 103	-18, 3	30, 79	-25, 3
Week 6	n	16	16	15	15
	Mean (SD)	64.5 (18.13)	-1.7 (3.53)	58.3 (12.65)	-7.1 (8.87)
	Median	60.0	-1.0	61.0	-6.0
	Min, Max	40, 102	-10, 3	30, 74	-24, 6
Week 8	n	16	16	14	14
	Mean (SD)	66.9 (19.59)	0.7 (12.68)	56.4 (10.62)	-10.4 (11.25)
	Median	65.5	-1.0	58.0	-7.0
	Min, Max	40, 103	-13, 46	37, 73	-31, 7
Week 12	n	15	15	14	14
	Mean (SD)	63.9 (17.53)	-2.9 (5.57)	55.1 (11.45)	-11.6 (10.97)
	Median	61.0	0.0	57.5	-8.5
	Min, Max	40, 100	-14, 2	30, 73	-33, 1
Week 16	n	14	14	14	14
	Mean (SD)	62.8 (19.04)	-3.9 (7.85)	55.1 (12.13)	-11.6 (12.70)
	Median	61.0	-0.5	55.0	-7.0
	Min, Max	40, 102	-17, 11	30, 73	-37, 3
Week 20	n	14	14	14	14
	Mean (SD)	64.4 (18.96)	-2.3 (6.79)	55.5 (14.85)	-11.3 (17.50)
	Median	62.5	0.0	53.0	-7.0
	Min, Max	40, 104	-13, 9	30, 89	-41, 23
Week 24	n	14	14	11	11
	Mean (SD)	62.6 (18.85)	-4.1 (9.10)	51.3 (12.04)	-17.2 (15.47)
	Median	58.5	0.0	51.0	-12.0
	Min, Max	40, 103	-18, 9	30, 73	-43, 0
Week 28	n	14	14	11	11
	Mean (SD)	64.4 (19.26)	-2.3 (9.66)	51.2 (11.99)	-17.3 (15.89)

Duration of illness (years) <5		Cohort 1 (N = 20)		Cohort 2 (N = 15)	
Visit	Statistics	Observed	Change	Observed	Change
	Median	58.0	0.0	50.0	-14.0
	Min, Max	43, 108	-17, 18	30, 73	-45, 0
Week 36	n	13	13	11	11
	Mean (SD)	61.3 (18.78)	-6.2 (10.17)	50.5 (14.04)	-18.0 (16.90)
	Median	55.0	-2.0	49.0	-14.0
	Min, Max	41, 99	-22, 6	30, 80	-46, 0
Week 44	n	12	12	10	10
	Mean (SD)	60.0 (20.97)	-5.5 (11.95)	50.4 (14.47)	-18.2 (16.96)
	Median	52.5	-1.5	48.0	-17.5
	Min, Max	40, 110	-29, 9	30, 81	-43, 1
Week 52	n	12	12	10	10
	Mean (SD)	61.5 (20.98)	-4.0 (13.82)	48.9 (13.57)	-19.7 (19.26)
	Median	55.5	-0.5	46.5	-15.0
	Min, Max	40, 112	-37, 12	30, 78	-48, 0
Week 52 (LOCF)	n	20	20	15	15
	Mean (SD)	62.0 (21.49)	-0.5 (16.66)	53.5 (15.64)	-11.9 (20.45)
	Median	57.0	0.0	49.0	-4.0
	Min, Max	31, 112	-37, 46	30, 89	-48, 23

Duration of illness (years) >=5 to <10		Cohort 1 (N = 24)		Cohort 2 (N = 24)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	24		24	
	Mean (SD)	61.4 (22.94)		63.3 (22.35)	
	Median	61.0		67.5	
	Min, Max	30, 119		30, 97	
Week 1	n	24	24	24	24
	Mean (SD)	60.7 (22.33)	-0.7 (3.18)	62.4 (21.93)	-0.9 (3.13)
	Median	58.5	0.0	65.0	0.0
	Min, Max	30, 116	-10, 5	30, 95	-9, 6

Duration of illness (years) >=5 to <10		Cohort 1 (N = 24)		Cohort 2 (N = 24)	
Visit	Statistics	Observed	Change	Observed	Change
Week 2	n	21	21	23	23
	Mean (SD)	56.3 (18.52)	-0.5 (3.36)	61.4 (22.46)	-1.5 (3.81)
	Median	53.0	0.0	65.0	0.0
	Min, Max	30, 99	-8, 6	30, 95	-11, 5
Week 4	n	20	20	23	23
	Mean (SD)	55.5 (19.26)	-0.8 (3.24)	61.2 (21.24)	-1.7 (5.50)
	Median	51.5	0.0	68.0	0.0
	Min, Max	30, 96	-10, 5	30, 98	-17, 8
Week 6	n	19	19	22	22
	Mean (SD)	56.3 (19.40)	-0.7 (3.45)	60.5 (21.88)	-2.6 (6.12)
	Median	57.0	0.0	63.5	0.0
	Min, Max	30, 93	-8, 7	30, 98	-16, 9
Week 8	n	19	19	22	22
	Mean (SD)	55.6 (20.51)	-1.4 (6.92)	59.6 (22.09)	-3.4 (7.46)
	Median	50.0	0.0	60.0	-1.0
	Min, Max	30, 93	-12, 21	30, 100	-19, 14
Week 12	n	18	18	22	22
	Mean (SD)	55.4 (20.44)	-1.9 (5.86)	58.8 (21.96)	-4.3 (7.79)
	Median	48.5	-0.5	60.0	-1.5
	Min, Max	30, 97	-12, 11	30, 94	-25, 10
Week 16	n	16	16	20	20
	Mean (SD)	50.7 (16.96)	-3.0 (5.38)	59.9 (21.05)	-6.1 (11.44)
	Median	44.5	-0.5	60.0	-2.5

Duration of illness (years) >=5 to <10		Cohort 1 (N = 24)		Cohort 2 (N = 24)	
Visit	Statistics	Observed	Change	Observed	Change
	Min, Max	30, 90	-16, 2	30, 95	-36, 12
Week 20	n	16	16	19	19
	Mean (SD)	51.2 (17.98)	-2.5 (6.00)	60.8 (22.88)	-5.0 (10.94)
	Median	45.5	0.0	60.0	-2.0
	Min, Max	30, 87	-15, 5	30, 98	-27, 17
Week 24	n	14	14	19	19
	Mean (SD)	49.5 (18.25)	-3.4 (6.02)	60.8 (24.50)	-5.0 (13.54)
	Median	42.0	-1.0	57.0	-1.0
	Min, Max	30, 88	-16, 4	30, 99	-38, 16
Week 28	n	14	14	19	19
	Mean (SD)	50.9 (19.17)	-2.1 (9.77)	60.4 (23.64)	-5.5 (11.90)
	Median	40.5	-0.5	57.0	-1.0
	Min, Max	34, 90	-23, 15	30, 99	-33, 8
Week 36	n	14	14	18	18
	Mean (SD)	49.7 (18.24)	-3.2 (7.00)	59.6 (23.89)	-6.0 (14.80)
	Median	43.0	0.0	60.0	-0.5
	Min, Max	30, 92	-18, 6	30, 100	-35, 23
Week 44	n	13	13	16	16
	Mean (SD)	49.5 (18.73)	-2.8 (7.66)	62.5 (27.78)	-2.4 (14.43)
	Median	41.0	0.0	58.5	-0.5
	Min, Max	30, 93	-19, 11	30, 117	-28, 26
Week 52	n	12	12	15	15
	Mean (SD)	50.7 (19.02)	-2.7 (7.45)	56.9 (22.63)	-6.3 (12.89)

Duration of illness (years) >=5 to <10		Cohort 1 (N = 24)		Cohort 2 (N = 24)	
Visit	Statistics	Observed	Change	Observed	Change
	Median	44.0	0.0	56.0	-7.0
	Min, Max	33, 92	-16, 6	30, 97	-29, 20
Week 52 (LOCF)	n	24	24	24	24
	Mean (SD)	60.5 (23.39)	-1.0 (6.22)	60.5 (24.59)	-2.9 (12.19)
	Median	52.5	0.0	60.0	0.0
	Min, Max	33, 116	-16, 11	30, 117	-29, 26

Duration of illness (years) >=10 to <20		Cohort 1 (N = 32)		Cohort 2 (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	32		31	
	Mean (SD)	57.7 (18.22)		64.2 (20.99)	
	Median	55.0		66.0	
	Min, Max	31, 92		33, 114	
Week 1	n	32	32	31	31
	Mean (SD)	57.3 (18.06)	-0.4 (1.68)	63.7 (20.75)	-0.5 (2.94)
	Median	55.0	0.0	64.0	0.0
	Min, Max	32, 93	-5, 3	30, 111	-6, 8
Week 2	n	29	29	29	29
	Mean (SD)	56.8 (16.60)	0.1 (5.75)	64.3 (20.54)	-1.0 (3.03)
	Median	56.0	0.0	67.0	0.0
	Min, Max	32, 96	-9, 26	30, 108	-7, 5
Week 4	n	28	28	30	30
	Mean (SD)	56.8 (16.77)	-0.5 (2.46)	63.3 (22.38)	-1.1 (5.80)
	Median	56.0	0.0	65.5	0.0
	Min, Max	33, 94	-8, 5	30, 118	-18, 10
Week 6	n	25	25	29	29
	Mean (SD)	56.7 (17.08)	-0.2 (6.55)	62.5 (21.39)	-1.6 (5.08)
	Median	56.0	0.0	65.0	-1.0
	Min, Max	31, 87	-15, 27	30, 108	-19, 14

Duration of illness (years) >=10 to <20		Cohort 1 (N = 32)		Cohort 2 (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change
Week 8	n	24	24	27	27
	Mean (SD)	55.1 (17.92)	-2.0 (5.17)	62.0 (21.86)	-1.8 (4.46)
	Median	52.0	-0.5	63.0	-1.0
	Min, Max	32, 98	-19, 9	30, 112	-12, 12
Week 12	n	24	24	26	26
	Mean (SD)	55.5 (18.74)	-1.6 (5.62)	61.1 (22.35)	-2.3 (5.17)
	Median	51.0	-1.0	62.5	-1.5
	Min, Max	33, 104	-18, 15	30, 114	-18, 8
Week 16	n	24	24	24	24
	Mean (SD)	54.9 (18.10)	-2.1 (4.79)	60.8 (23.33)	-2.2 (5.14)
	Median	51.0	-1.0	62.0	-1.5
	Min, Max	32, 96	-14, 7	30, 114	-14, 10
Week 20	n	24	24	23	23
	Mean (SD)	55.6 (18.57)	-1.4 (5.54)	61.3 (23.54)	-1.6 (5.36)
	Median	50.5	-0.5	65.0	-1.0
	Min, Max	31, 102	-14, 13	30, 116	-13, 9
Week 24	n	24	24	21	21
	Mean (SD)	55.0 (18.55)	-2.0 (5.57)	62.2 (23.85)	-3.0 (7.85)
	Median	50.0	-0.5	62.0	-2.0
	Min, Max	31, 102	-17, 13	30, 122	-27, 8
Week 28	n	24	24	19	19
	Mean (SD)	57.8 (23.37)	0.7 (12.51)	59.4 (20.93)	-3.3 (6.80)
	Median	50.0	0.0	60.0	-1.0
	Min, Max	32, 128	-17, 53	30, 95	-20, 7
Week 36	n	23	23	19	19
	Mean (SD)	54.5 (17.28)	-1.7 (5.11)	58.8 (21.00)	-3.8 (7.95)
	Median	50.0	0.0	62.0	-2.0
	Min, Max	31, 89	-17, 7	30, 94	-28, 8
Week 44	n	22	22	18	18
	Mean (SD)	55.2 (19.59)	-0.7 (6.82)	56.7 (19.77)	-4.9 (8.29)
	Median	46.0	-0.5	54.5	-2.5
	Min, Max	32, 103	-17, 16	30, 91	-32, 7
Week 52	n	20	20	18	18

Duration of illness (years) >=10 to <20		Cohort 1 (N = 32)		Cohort 2 (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change
	Mean (SD)	51.3 (16.88)	-3.0 (5.12)	58.9 (24.53)	-2.7 (12.47)
	Median	42.0	-1.5	53.5	-3.5
	Min, Max	31, 85	-18, 5	30, 117	-28, 37
Week 52 (LOCF)	n	32	32	31	31
	Mean (SD)	59.8 (23.22)	2.0 (13.12)	63.7 (24.26)	-0.5 (11.04)
	Median	56.5	0.0	64.0	-1.0
	Min, Max	31, 128	-18, 53	30, 122	-28, 37

Duration of illness (years) >=20		Cohort 1 (N = 21)		Cohort 2 (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	21		31	
	Mean (SD)	76.0 (20.22)		73.5 (21.05)	
	Median	80.0		74.0	
	Min, Max	31, 102		34, 119	
Week 1	n	21	21	31	31
	Mean (SD)	76.5 (20.79)	0.4 (2.69)	73.3 (21.03)	-0.2 (5.11)
	Median	79.0	0.0	71.0	0.0
	Min, Max	31, 104	-6, 9	34, 121	-18, 10
Week 2	n	20	20	31	31
	Mean (SD)	76.6 (21.26)	0.1 (3.60)	72.8 (21.48)	-0.7 (8.73)
	Median	81.0	0.0	69.0	0.0
	Min, Max	31, 109	-9, 7	34, 125	-15, 33
Week 4	n	21	21	30	30
	Mean (SD)	75.6 (21.57)	-0.5 (4.50)	70.6 (23.12)	-3.2 (7.61)
	Median	76.0	0.0	67.0	-1.5
	Min, Max	32, 116	-10, 14	34, 134	-30, 15
Week 6	n	20	20	28	28
	Mean (SD)	75.6 (22.77)	0.1 (6.68)	68.5 (19.72)	-4.0 (8.28)
	Median	74.5	0.0	68.5	-2.0
	Min, Max	32, 127	-10, 25	34, 107	-32, 16
Week 8	n	19	19	26	26
	Mean (SD)	74.2 (23.29)	-0.3 (7.16)	66.2 (21.85)	-6.0 (10.72)
	Median	69.0	0.0	63.5	-3.0

Duration of illness (years) >=20		Cohort 1 (N = 21)		Cohort 2 (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change
	Min, Max	32, 123	-10, 21	34, 107	-35, 18
Week 12	n	18	18	25	25
	Mean (SD)	71.9 (22.93)	-1.4 (6.99)	67.1 (21.16)	-5.5 (13.68)
	Median	67.5	0.0	64.0	-4.0
	Min, Max	31, 115	-14, 13	33, 106	-41, 33
Week 16	n	17	17	24	24
	Mean (SD)	69.1 (21.29)	-2.7 (6.88)	67.1 (21.33)	-7.0 (11.75)
	Median	65.0	-1.0	63.5	-3.5
	Min, Max	30, 109	-16, 10	34, 108	-34, 19
Week 20	n	15	15	22	22
	Mean (SD)	69.7 (22.83)	-2.2 (7.90)	65.1 (19.72)	-7.5 (9.98)
	Median	67.0	-1.0	61.0	-5.0
	Min, Max	30, 105	-17, 14	34, 105	-29, 4
Week 24	n	15	15	21	21
	Mean (SD)	68.3 (21.37)	-3.6 (6.13)	65.0 (20.91)	-8.5 (11.86)
	Median	64.0	-1.0	60.0	-4.0
	Min, Max	30, 102	-17, 5	34, 105	-37, 8
Week 28	n	15	15	20	20
	Mean (SD)	69.4 (23.13)	-2.5 (7.50)	64.2 (21.24)	-9.3 (13.03)
	Median	64.0	-2.0	59.0	-5.5
	Min, Max	30, 107	-16, 13	34, 105	-37, 11
Week 36	n	13	13	19	19
	Mean (SD)	64.1 (19.47)	-4.0 (7.25)	64.5 (21.60)	-7.9 (14.83)
	Median	65.0	-3.0	59.0	-3.0
	Min, Max	30, 95	-16, 10	34, 105	-37, 23
Week 44	n	13	13	17	17
	Mean (SD)	64.6 (19.63)	-3.5 (8.10)	61.7 (21.24)	-10.8 (13.22)
	Median	63.0	-3.0	59.0	-9.0
	Min, Max	30, 94	-18, 9	34, 104	-35, 11
Week 52	n	13	13	17	17
	Mean (SD)	63.2 (18.62)	-4.8 (7.70)	59.9 (21.73)	-12.5 (13.54)
	Median	64.0	-4.0	57.0	-9.0
	Min, Max	30, 93	-21, 8	34, 104	-40, 1

Duration of illness (years) >=20		Cohort 1 (N = 21)		Cohort 2 (N = 31)	
Visit	Statistics	Observed	Change	Observed	Change
Week 52 (LOCF)	n	21	21	31	31
	Mean (SD)	74.0 (21.93)	-2.1 (7.60)	69.9 (23.56)	-3.5 (17.34)
	Median	71.0	-1.0	67.0	-2.0
	Min, Max	30, 107	-21, 13	34, 134	-40, 33

Duration of illness (years) Unknown		Cohort 1 (N = 0)		Cohort 2 (N = 2)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	0		2	
	Mean (SD)	. (.)		93.0 (21.21)	
	Median	.		93.0	
	Min, Max	., .		78, 108	
Week 1	n	0	0	2	2
	Mean (SD)	. (.)	. (.)	94.0 (18.38)	1.0 (2.83)
	Median	.	.	94.0	1.0
	Min, Max	., .	., .	81, 107	-1, 3
Week 2	n	0	0	2	2
	Mean (SD)	. (.)	. (.)	92.0 (21.21)	-1.0 (0.00)
	Median	.	.	92.0	-1.0
	Min, Max	., .	., .	77, 107	-1, -1
Week 4	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	79.0 (.)	1.0 (.)
	Median	.	.	79.0	1.0
	Min, Max	., .	., .	79, 79	1, 1
Week 6	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	82.0 (.)	4.0 (.)
	Median	.	.	82.0	4.0
	Min, Max	., .	., .	82, 82	4, 4
Week 8	n	0	0	1	1
	Mean (SD)	. (.)	. (.)	88.0 (.)	10.0 (.)
	Median	.	.	88.0	10.0
	Min, Max	., .	., .	88, 88	10, 10
Week 12	n	0	0	1	1

Duration of illness (years) Unknown		Cohort 1 (N = 0)		Cohort 2 (N = 2)	
Visit	Statistics	Observed	Change	Observed	Change
	Mean (SD)	. (.)	. (.)	98.0 (.)	20.0 (.)
	Median	.	.	98.0	20.0
	Min, Max	., .	., .	98, 98	20, 20
Week 16	n	0	0	0	0
	Mean (SD)	. (.)	. (.)	. (.)	. (.)
	Median	.	.	.	.
	Min, Max	., .	., .	., .	., .
Week 20	n	0	0	0	0
	Mean (SD)	. (.)	. (.)	. (.)	. (.)
	Median	.	.	.	.
	Min, Max	., .	., .	., .	., .
Week 24	n	0	0	0	0
	Mean (SD)	. (.)	. (.)	. (.)	. (.)
	Median	.	.	.	.
	Min, Max	., .	., .	., .	., .
Week 28	n	0	0	0	0
	Mean (SD)	. (.)	. (.)	. (.)	. (.)
	Median	.	.	.	.
	Min, Max	., .	., .	., .	., .
Week 36	n	0	0	0	0
	Mean (SD)	. (.)	. (.)	. (.)	. (.)
	Median	.	.	.	.
	Min, Max	., .	., .	., .	., .
Week 44	n	0	0	0	0
	Mean (SD)	. (.)	. (.)	. (.)	. (.)
	Median	.	.	.	.
	Min, Max	., .	., .	., .	., .
Week 52	n	0	0	0	0
	Mean (SD)	. (.)	. (.)	. (.)	. (.)
	Median	.	.	.	.
	Min, Max	., .	., .	., .	., .
Week 52 (LOCF)	n	0	0	2	2
	Mean (SD)	. (.)	. (.)	102.5 (6.36)	9.5 (14.85)

Duration of illness (years) Unknown		Cohort 1 (N = 0)		Cohort 2 (N = 2)	
Visit	Statistics	Observed	Change	Observed	Change
	Median	.	.	102.5	9.5
	Min, Max	., .	., .	98, 107	-1, 20

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-51　PANSS 合計スコア変化量
（40 試験：ロナセンテープ貼付期、入院・外来の別）

安全性解析対象集団

Hospitalization Status at Screening Inpatient		Cohort 1 (N = 8)		Cohort 2 (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	8		17	
	Mean (SD)	78.3 (24.57)		87.2 (17.40)	
	Median	87.5		89.0	
	Min, Max	31, 100		46, 119	
Week 1	n	8	8	17	17
	Mean (SD)	78.1 (24.69)	-0.1 (0.64)	86.2 (17.27)	-0.9 (4.19)
	Median	87.0	0.0	86.0	-1.0
	Min, Max	31, 100	-1, 1	56, 121	-8, 10
Week 2	n	7	7	17	17
	Mean (SD)	84.3 (16.90)	-0.7 (1.38)	85.4 (17.68)	-1.8 (6.47)
	Median	94.0	0.0	83.0	-2.0
	Min, Max	54, 100	-3, 1	62, 125	-9, 16
Week 4	n	7	7	17	17
	Mean (SD)	84.4 (16.39)	-0.6 (1.81)	84.2 (20.42)	-2.9 (6.22)
	Median	94.0	0.0	83.0	-4.0
	Min, Max	56, 100	-4, 2	46, 134	-12, 15
Week 6	n	7	7	16	16
	Mean (SD)	87.1 (11.60)	2.1 (11.35)	79.6 (16.95)	-5.6 (4.69)
	Median	94.0	-1.0	81.5	-6.5
	Min, Max	70, 99	-5, 27	46, 107	-14, 0
Week 8	n	5	5	16	16
	Mean (SD)	85.8 (13.10)	-3.2 (3.11)	76.9 (18.76)	-8.3 (9.62)
	Median	95.0	-4.0	76.5	-6.0

Hospitalization Status at Screening Inpatient		Cohort 1 (N = 8)		Cohort 2 (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change
	Min, Max	70, 96	-7, 0	46, 107	-31, 2
Week 12	n	4	4	16	16
	Mean (SD)	82.3 (18.26)	-5.3 (6.70)	76.4 (19.05)	-8.8 (10.01)
	Median	81.5	-3.5	79.0	-6.0
	Min, Max	66, 100	-14, 0	46, 106	-33, 1
Week 16	n	3	3	16	16
	Mean (SD)	75.0 (18.19)	-8.3 (8.02)	74.8 (19.80)	-10.4 (10.95)
	Median	65.0	-9.0	77.5	-8.0
	Min, Max	64, 96	-16, 0	46, 106	-37, 1
Week 20	n	3	3	16	16
	Mean (SD)	72.3 (17.93)	-11.0 (7.21)	74.8 (19.72)	-10.4 (10.86)
	Median	63.0	-13.0	77.5	-8.5
	Min, Max	61, 93	-17, -3	45, 105	-35, 1
Week 24	n	3	3	16	16
	Mean (SD)	71.3 (18.93)	-12.0 (7.81)	75.5 (20.49)	-9.7 (13.12)
	Median	63.0	-16.0	81.5	-8.0
	Min, Max	58, 93	-17, -3	46, 105	-38, 8
Week 28	n	3	3	15	15
	Mean (SD)	71.3 (19.09)	-12.0 (7.81)	74.4 (21.76)	-11.5 (13.84)
	Median	64.0	-16.0	73.0	-11.0
	Min, Max	57, 93	-17, -3	45, 105	-38, 8
Week 36	n	3	3	14	14
	Mean (SD)	70.7 (20.11)	-12.7 (8.74)	74.1 (22.52)	-11.3 (14.46)
	Median	65.0	-15.0	74.5	-6.5
	Min, Max	54, 93	-20, -3	45, 105	-38, 7
Week 44	n	3	3	13	13
	Mean (SD)	69.0 (21.63)	-14.3 (10.26)	72.1 (22.46)	-13.2 (14.30)
	Median	63.0	-17.0	68.0	-11.0
	Min, Max	51, 93	-23, -3	45, 104	-38, 3
Week 52	n	3	3	13	13
	Mean (SD)	68.3 (21.50)	-15.0 (10.15)	69.9 (24.16)	-15.4 (16.19)
	Median	63.0	-17.0	70.0	-13.0
	Min, Max	50, 92	-24, -4	39, 104	-48, 2

Hospitalization Status at Screening Inpatient		Cohort 1 (N = 8)		Cohort 2 (N = 17)	
Visit	Statistics	Observed	Change	Observed	Change
Week 52 (LOCF)	n	8	8	17	17
	Mean (SD)	76.4 (25.68)	-1.9 (15.08)	76.2 (26.32)	-11.0 (17.02)
	Median	86.5	0.0	80.0	-4.0
	Min, Max	31, 100	-24, 27	39, 134	-48, 15

Hospitalization Status at Screening Outpatient		Cohort 1 (N = 89)		Cohort 2 (N = 86)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	89		86	
	Mean (SD)	62.3 (20.55)		63.6 (19.92)	
	Median	61.0		65.5	
	Min, Max	30, 119		30, 114	
Week 1	n	89	89	86	86
	Mean (SD)	61.8 (20.49)	-0.5 (3.29)	62.6 (19.49)	-1.0 (4.29)
	Median	61.0	0.0	64.0	0.0
	Min, Max	30, 116	-16, 9	30, 111	-20, 9
Week 2	n	82	82	83	83
	Mean (SD)	60.2 (19.15)	-0.6 (5.39)	62.5 (19.67)	-1.4 (5.89)
	Median	59.0	0.0	63.0	0.0
	Min, Max	30, 109	-22, 26	30, 108	-22, 33
Week 4	n	80	80	82	82
	Mean (SD)	60.6 (19.31)	-0.9 (3.90)	60.6 (19.25)	-2.5 (6.89)
	Median	58.0	0.0	62.5	0.0
	Min, Max	30, 116	-18, 14	30, 118	-30, 10
Week 6	n	73	73	79	79
	Mean (SD)	60.6 (19.82)	-0.8 (4.54)	60.1 (18.92)	-2.9 (7.52)
	Median	58.0	0.0	62.0	0.0
	Min, Max	30, 127	-15, 25	30, 108	-32, 16
Week 8	n	73	73	74	74
	Mean (SD)	60.7 (21.07)	-0.7 (8.19)	58.8 (19.65)	-3.8 (8.71)
	Median	58.0	0.0	60.0	-2.0
	Min, Max	30, 123	-19, 46	30, 112	-35, 18
Week 12	n	71	71	72	72

Hospitalization Status at Screening Outpatient		Cohort 1 (N = 89)		Cohort 2 (N = 86)	
Visit	Statistics	Observed	Change	Observed	Change
	Mean (SD)	59.9 (20.38)	-1.7 (5.87)	58.4 (19.95)	-4.1 (10.38)
	Median	57.0	0.0	60.0	-2.0
	Min, Max	30, 115	-18, 15	30, 114	-41, 33
Week 16	n	68	68	66	66
	Mean (SD)	58.2 (19.61)	-2.6 (5.89)	58.2 (19.72)	-5.1 (10.40)
	Median	55.5	-1.0	60.0	-2.0
	Min, Max	30, 109	-17, 11	30, 114	-36, 19
Week 20	n	66	66	62	62
	Mean (SD)	58.8 (20.36)	-1.6 (6.05)	57.7 (19.79)	-4.7 (11.15)
	Median	56.0	0.0	57.0	-1.0
	Min, Max	30, 105	-15, 14	30, 116	-41, 23
Week 24	n	64	64	56	56
	Mean (SD)	57.8 (19.97)	-2.7 (6.25)	56.9 (20.52)	-6.6 (12.53)
	Median	56.0	-0.5	53.5	-1.5
	Min, Max	30, 103	-18, 13	30, 122	-43, 16
Week 28	n	64	64	54	54
	Mean (SD)	59.8 (22.33)	-0.7 (10.16)	55.7 (18.63)	-6.9 (12.07)
	Median	55.5	0.0	54.5	-2.0
	Min, Max	30, 128	-23, 53	30, 99	-45, 11
Week 36	n	60	60	53	53
	Mean (SD)	56.1 (18.43)	-3.0 (6.93)	55.4 (19.08)	-7.0 (14.04)
	Median	53.5	0.0	52.0	-2.0
	Min, Max	30, 99	-22, 10	30, 100	-46, 23
Week 44	n	57	57	48	48
	Mean (SD)	56.3 (19.82)	-2.1 (8.01)	54.9 (20.32)	-6.7 (13.54)
	Median	50.0	0.0	48.0	-3.0
	Min, Max	30, 110	-29, 16	30, 117	-43, 26
Week 52	n	54	54	47	47
	Mean (SD)	55.4 (18.84)	-2.9 (7.94)	53.5 (19.63)	-7.5 (14.47)
	Median	54.5	-1.0	47.0	-4.0
	Min, Max	30, 112	-37, 12	30, 117	-44, 37
Week 52 (LOCF)	n	89	89	86	86
	Mean (SD)	62.3 (22.52)	0.0 (11.33)	61.7 (22.66)	-1.9 (14.58)

Hospitalization Status at Screening Outpatient		Cohort 1 (N = 89)		Cohort 2 (N = 86)	
Visit	Statistics	Observed	Change	Observed	Change
	Median	59.0	0.0	61.0	0.0
	Min, Max	30, 128	-37, 53	30, 122	-44, 37

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-52　PANSS 合計スコア変化量

（40 試験：ロナセンテープ貼付期、ベースライン PANSS 合計スコア別）

安全性解析対象集団

Baseline PANSS Total Score 59 or less		Cohort 1 (N = 40)		Cohort 2 (N = 32)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	40		32	
	Mean (SD)	42.9 (8.47)		42.0 (8.32)	
	Median	42.0		40.5	
	Min, Max	30, 58		30, 58	
Week 1	n	40	40	32	32
	Mean (SD)	43.1 (8.38)	0.2 (1.14)	42.3 (9.55)	0.3 (3.14)
	Median	43.0	0.0	41.0	0.0
	Min, Max	30, 58	-2, 5	30, 64	-7, 10
Week 2	n	38	38	30	30
	Mean (SD)	44.3 (8.70)	0.9 (4.40)	41.6 (9.28)	-0.1 (3.96)
	Median	43.5	0.0	41.0	0.0
	Min, Max	30, 65	-2, 26	30, 62	-7, 16
Week 4	n	36	36	31	31
	Mean (SD)	43.9 (7.90)	0.0 (1.28)	41.3 (8.55)	-0.2 (2.81)
	Median	42.0	0.0	40.0	0.0
	Min, Max	30, 58	-3, 3	30, 58	-7, 8
Week 6	n	32	32	31	31
	Mean (SD)	42.9 (7.93)	-0.3 (1.25)	41.7 (9.95)	0.2 (4.27)
	Median	42.0	0.0	40.0	0.0
	Min, Max	30, 57	-3, 3	30, 74	-7, 16
Week 8	n	32	32	30	30
	Mean (SD)	44.1 (13.06)	0.9 (8.33)	40.4 (7.70)	-1.0 (3.60)
	Median	42.0	0.0	38.5	0.0

Baseline PANSS Total Score 59 or less		Cohort 1 (N = 40)		Cohort 2 (N = 32)	
Visit	Statistics	Observed	Change	Observed	Change
	Min, Max	30, 103	-5, 46	30, 58	-12, 7
Week 12	n	30	30	30	30
	Mean (SD)	42.1 (7.79)	-0.4 (1.89)	40.9 (9.70)	-0.4 (7.05)
	Median	41.0	0.0	39.0	0.0
	Min, Max	30, 57	-5, 5	30, 70	-10, 33
Week 16	n	30	30	27	27
	Mean (SD)	41.9 (7.77)	-0.6 (1.81)	40.9 (8.70)	-1.2 (4.08)
	Median	41.0	0.0	41.0	0.0
	Min, Max	30, 57	-6, 2	30, 62	-14, 7
Week 20	n	30	30	27	27
	Mean (SD)	42.1 (7.93)	-0.4 (2.57)	41.1 (8.45)	-0.9 (4.12)
	Median	41.5	0.0	41.0	0.0
	Min, Max	30, 58	-8, 7	30, 59	-12, 8
Week 24	n	29	29	23	23
	Mean (SD)	42.0 (8.51)	-0.4 (2.95)	40.3 (7.61)	-1.3 (4.06)
	Median	39.0	0.0	40.0	0.0
	Min, Max	30, 59	-8, 9	30, 58	-10, 8
Week 28	n	29	29	23	23
	Mean (SD)	42.6 (7.90)	0.1 (3.94)	40.2 (7.63)	-1.4 (3.68)
	Median	42.0	0.0	40.0	0.0
	Min, Max	30, 59	-8, 12	30, 58	-12, 6
Week 36	n	29	29	23	23
	Mean (SD)	42.4 (8.24)	0.0 (3.90)	40.9 (10.95)	-0.7 (6.65)
	Median	41.0	0.0	39.0	0.0
	Min, Max	30, 56	-9, 7	30, 81	-11, 23
Week 44	n	29	29	21	21
	Mean (SD)	42.8 (9.41)	0.3 (5.18)	39.0 (6.68)	-1.6 (4.25)
	Median	40.0	0.0	38.0	0.0
	Min, Max	30, 72	-9, 16	30, 54	-11, 7
Week 52	n	27	27	21	21
	Mean (SD)	41.7 (8.03)	-0.3 (4.82)	38.4 (6.41)	-2.1 (5.09)
	Median	39.0	0.0	37.0	-1.0
	Min, Max	30, 58	-11, 12	30, 54	-15, 8

Baseline PANSS Total Score 59 or less		Cohort 1 (N = 40)		Cohort 2 (N = 32)	
Visit	Statistics	Observed	Change	Observed	Change
Week 52 (LOCF)	n	40	40	32	32
	Mean (SD)	45.0 (13.61)	2.1 (9.50)	42.9 (12.22)	1.0 (8.78)
	Median	41.0	0.0	41.0	0.0
	Min, Max	30, 103	-11, 46	30, 81	-15, 33

Baseline PANSS Total Score 60 to 79		Cohort 1 (N = 30)		Cohort 2 (N = 42)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	30		42	
	Mean (SD)	68.4 (9.01)		69.2 (5.59)	
	Median	67.5		69.5	
	Min, Max	54, 101		60, 79	
Week 1	n	30	30	42	42
	Mean (SD)	67.1 (9.58)	-1.3 (3.37)	68.1 (6.35)	-1.1 (4.06)
	Median	66.5	0.0	69.0	-0.5
	Min, Max	50, 99	-10, 8	56, 81	-18, 9
Week 2	n	27	27	41	41
	Mean (SD)	66.0 (10.16)	-1.7 (5.10)	68.2 (8.02)	-0.9 (6.78)
	Median	66.0	0.0	67.0	-1.0
	Min, Max	41, 99	-18, 7	48, 96	-15, 33
Week 4	n	27	27	40	40
	Mean (SD)	65.8 (9.47)	-1.9 (3.83)	66.2 (8.63)	-3.1 (7.33)
	Median	66.0	-1.0	67.0	-1.5
	Min, Max	50, 96	-10, 5	44, 86	-30, 10
Week 6	n	27	27	37	37
	Mean (SD)	67.0 (8.53)	-0.7 (7.36)	65.9 (9.26)	-3.6 (7.75)
	Median	67.0	-1.0	65.0	-2.0
	Min, Max	57, 93	-15, 27	42, 90	-32, 14
Week 8	n	26	26	34	34
	Mean (SD)	64.9 (10.91)	-3.3 (7.28)	64.9 (10.17)	-4.7 (9.16)
	Median	64.0	-3.0	64.5	-3.5
	Min, Max	45, 93	-19, 21	39, 91	-35, 14
Week 12	n	26	26	32	32

Baseline PANSS Total Score 60 to 79		Cohort 1 (N = 30)		Cohort 2 (N = 42)	
Visit	Statistics	Observed	Change	Observed	Change
	Mean (SD)	64.4 (11.22)	-3.8 (6.29)	64.0 (11.06)	-5.7 (10.78)
	Median	65.5	-3.0	62.0	-4.5
	Min, Max	46, 97	-18, 11	33, 98	-41, 20
Week 16	n	23	23	29	29
	Mean (SD)	61.3 (9.99)	-5.3 (7.18)	62.7 (10.26)	-6.8 (10.40)
	Median	64.0	-3.0	63.0	-3.0
	Min, Max	42, 78	-17, 11	38, 89	-34, 12
Week 20	n	21	21	27	27
	Mean (SD)	61.5 (9.07)	-4.7 (6.93)	64.1 (11.52)	-5.5 (11.64)
	Median	64.0	-3.0	65.0	-4.0
	Min, Max	45, 78	-15, 9	41, 94	-28, 23
Week 24	n	21	21	25	25
	Mean (SD)	60.2 (10.19)	-6.0 (7.18)	61.9 (12.22)	-8.0 (11.87)
	Median	64.0	-5.0	62.0	-7.0
	Min, Max	43, 78	-17, 9	37, 93	-37, 16
Week 28	n	21	21	23	23
	Mean (SD)	61.7 (11.78)	-4.5 (9.81)	60.9 (11.01)	-9.0 (11.49)
	Median	65.0	-3.0	60.0	-9.0
	Min, Max	38, 79	-23, 18	37, 85	-37, 11
Week 36	n	20	20	22	22
	Mean (SD)	60.8 (11.42)	-6.1 (7.58)	60.8 (13.15)	-9.1 (13.57)
	Median	64.5	-2.0	61.0	-9.0
	Min, Max	43, 78	-18, 3	37, 100	-37, 23
Week 44	n	18	18	21	21
	Mean (SD)	61.4 (11.90)	-5.9 (7.36)	60.3 (13.80)	-9.7 (14.27)
	Median	63.5	-3.5	60.0	-9.0
	Min, Max	41, 80	-19, 8	40, 102	-33, 25
Week 52	n	18	18	21	21
	Mean (SD)	61.5 (9.97)	-5.8 (5.76)	59.2 (13.38)	-10.8 (13.67)
	Median	64.5	-4.5	60.0	-9.0
	Min, Max	42, 78	-18, 0	37, 97	-37, 20
Week 52 (LOCF)	n	30	30	42	42
	Mean (SD)	66.2 (11.99)	-2.2 (9.04)	65.7 (14.99)	-3.5 (14.52)

Baseline PANSS Total Score 60 to 79		Cohort 1 (N = 30)		Cohort 2 (N = 42)	
Visit	Statistics	Observed	Change	Observed	Change
	Median	67.0	-2.0	64.5	-1.0
	Min, Max	42, 97	-18, 27	37, 98	-37, 33

Baseline PANSS Total Score 80 or above		Cohort 1 (N = 27)		Cohort 2 (N = 29)	
Visit	Statistics	Observed	Change	Observed	Change
Baseline	n	27		29	
	Mean (SD)	88.9 (10.51)		93.2 (10.12)	
	Median	89.0		91.0	
	Min, Max	73, 119		80, 119	
Week 1	n	27	27	29	29
	Mean (SD)	88.4 (12.35)	-0.6 (4.54)	91.0 (12.34)	-2.2 (5.21)
	Median	90.0	0.0	91.0	-1.0
	Min, Max	63, 116	-16, 9	62, 121	-20, 8
Week 2	n	24	24	29	29
	Mean (SD)	86.0 (12.41)	-1.8 (5.98)	89.4 (13.40)	-3.8 (5.97)
	Median	87.0	-1.0	90.0	-3.0
	Min, Max	57, 109	-22, 7	60, 125	-22, 10
Week 4	n	24	24	28	28
	Mean (SD)	86.7 (12.36)	-1.1 (5.62)	88.3 (15.98)	-4.4 (8.28)
	Median	87.0	0.0	84.5	-4.5
	Min, Max	61, 116	-18, 14	57, 134	-25, 15
Week 6	n	21	21	27	27
	Mean (SD)	88.0 (12.83)	-0.8 (6.52)	84.7 (12.69)	-7.0 (7.29)
	Median	87.0	-2.0	82.0	-7.0
	Min, Max	70, 127	-10, 25	58, 108	-24, 5
Week 8	n	20	20	26	26
	Mean (SD)	88.0 (13.47)	-0.5 (7.79)	83.3 (16.22)	-8.7 (11.31)
	Median	89.5	-1.0	82.0	-7.0
	Min, Max	69, 123	-13, 21	56, 112	-31, 18
Week 12	n	19	19	26	26
	Mean (SD)	86.5 (14.27)	-1.6 (8.62)	82.8 (16.32)	-9.2 (11.53)
	Median	85.0	-1.0	86.0	-7.0
	Min, Max	66, 115	-14, 15	54, 114	-33, 16

Baseline PANSS Total Score 80 or above		Cohort 1 (N = 27)		Cohort 2 (N = 29)	
Visit	Statistics	Observed	Change	Observed	Change
Week 16	n	18	18	26	26
	Mean (SD)	84.2 (13.18)	-3.2 (7.76)	81.4 (17.83)	-10.6 (13.47)
	Median	84.5	-1.5	85.0	-8.5
	Min, Max	64, 109	-16, 10	50, 114	-37, 19
Week 20	n	18	18	24	24
	Mean (SD)	85.9 (13.16)	-1.6 (8.90)	80.5 (18.76)	-11.8 (13.69)
	Median	84.5	0.0	84.5	-8.5
	Min, Max	61, 105	-17, 14	49, 116	-41, 6
Week 24	n	17	17	24	24
	Mean (SD)	84.3 (13.57)	-4.0 (8.54)	79.9 (21.38)	-12.4 (16.32)
	Median	85.0	-3.0	82.5	-9.5
	Min, Max	58, 103	-18, 13	47, 122	-43, 8
Week 28	n	17	17	23	23
	Mean (SD)	88.8 (17.69)	0.5 (16.37)	78.1 (19.76)	-13.2 (16.26)
	Median	90.0	-2.0	83.0	-11.0
	Min, Max	57, 128	-17, 53	45, 105	-45, 8
Week 36	n	14	14	22	22
	Mean (SD)	81.1 (13.67)	-6.9 (9.21)	77.0 (20.05)	-14.3 (17.19)
	Median	82.0	-4.5	81.5	-12.0
	Min, Max	54, 99	-22, 10	44, 105	-46, 8
Week 44	n	13	13	19	19
	Mean (SD)	82.5 (17.80)	-5.2 (12.99)	78.4 (21.32)	-13.4 (17.63)
	Median	85.0	-1.0	85.0	-12.0
	Min, Max	51, 110	-29, 14	47, 117	-43, 26
Week 52	n	12	12	18	18
	Mean (SD)	80.0 (18.84)	-7.6 (14.20)	76.2 (23.17)	-15.7 (20.71)
	Median	82.0	-2.0	81.0	-14.0
	Min, Max	49, 112	-37, 9	39, 117	-48, 37
Week 52 (LOCF)	n	27	27	29	29
	Mean (SD)	87.9 (18.96)	-1.1 (16.00)	85.1 (24.41)	-8.1 (20.34)
	Median	92.0	0.0	89.0	-7.0
	Min, Max	49, 128	-37, 53	39, 134	-48, 37

Baseline PANSS Total Score 80 or above		Cohort 1 (N = 27)		Cohort 2 (N = 29)	
Visit	Statistics	Observed	Change	Observed	Change

Summary statistics for the observed value and change from baseline value (denoted by change) are based on subjects with both a baseline and the target visit observation. Week 52 (LOCF) endpoint is the last post-baseline observation in the DSP-5423P treatment phase up to 7 days after the final application of DSP-5423P.

表 2.7.3.6-53　Week 28 時点の DAI-10 合計スコア別ロナセンテープ貼付期間
（40 試験：ロナセンテープ貼付期）

安全性解析対象集団

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
DAI-10 total score at Week 28 : -10			
Duration of exposure (days)			
n	0	1	1
Mean (SD)	. (.)	160 (.)	160 (.)
Median	.	.	.
Min, Max	., .	., .	., .
DAI-10 total score at Week 28 : -8			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
DAI-10 total score at Week 28 : -6			
Duration of exposure (days)			
n	1	3	4
Mean (SD)	54 (.)	154.7 (99.38)	129.5 (95.49)
Median	.	106.0	97.5
Min, Max	., .	89, 269	54, 269
DAI-10 total score at Week 28 : -4			
Duration of exposure (days)			
n	3	3	6
Mean (SD)	192.7 (102.16)	239.0 (120.75)	215.8 (103.21)
Median	226.0	230.0	228.0
Min, Max	78, 274	123, 364	78, 364
DAI-10 total score at Week 28 : -2			
Duration of exposure (days)			
n	4	1	5
Mean (SD)	190.5 (125.57)	350 (.)	222.4 (130.05)

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Median	160.5	.	196.0
Min, Max	77, 364	., .	77, 364
DAI-10 total score at Week 28 : 0			
Duration of exposure (days)			
n	6	9	15
Mean (SD)	258.3 (161.03)	258.1 (104.92)	258.2 (124.71)
Median	359.5	282.0	315.0
Min, Max	49, 366	66, 365	49, 366
DAI-10 total score at Week 28 : 2			
Duration of exposure (days)			
n	14	11	25
Mean (SD)	330.1 (81.30)	274.0 (127.75)	305.4 (105.77)
Median	361.0	355.0	357.0
Min, Max	93, 366	63, 371	63, 371
DAI-10 total score at Week 28 : 4			
Duration of exposure (days)			
n	8	6	14
Mean (SD)	283.1 (104.84)	233.8 (150.02)	262.0 (123.35)
Median	330.5	246.5	330.5
Min, Max	77, 368	56, 375	56, 375
DAI-10 total score at Week 28 : 6			
Duration of exposure (days)			
n	10	16	26
Mean (SD)	314.7 (86.49)	339.8 (55.51)	330.2 (68.54)
Median	360.0	358.5	358.5
Min, Max	112, 364	195, 378	112, 378
DAI-10 total score at Week 28 : 8			
Duration of exposure (days)			
n	19	20	39
Mean (SD)	344.3 (69.25)	291.0 (114.21)	316.9 (97.59)
Median	364.0	356.5	357.0
Min, Max	60, 371	53, 371	53, 371
DAI-10 total score at Week 28 : 10			
Duration of exposure (days)			
n	12	19	31
Mean (SD)	346.8 (53.34)	320.6 (99.40)	330.7 (84.49)

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Median	364.0	364.0	364.0
Min, Max	178, 368	84, 377	84, 377

Duration of exposure (days) = the last application date - first application date + 1.

表 2.7.3.6-54　Week 28 時点の DAI-10 合計スコア別治験完了割合
（40 試験：ロナセンテープ貼付期）

安全性解析対象集団

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
DAI-10 total score at Week 28 : -10			
n	0	1	1
Completed	0	0	0
Discontinued	0	1 (1.0)	1 (0.5)
DAI-10 total score at Week 28 : -8			
n	0	0	0
Completed	0	0	0
Discontinued	0	0	0
DAI-10 total score at Week 28 : -6			
n	1	3	4
Completed	0	0	0
Discontinued	1 (1.0)	3 (2.9)	4 (2.0)
DAI-10 total score at Week 28 : -4			
n	3	3	6
Completed	0	1 (1.0)	1 (0.5)
Discontinued	3 (3.1)	2 (1.9)	5 (2.5)
DAI-10 total score at Week 28 : -2			
n	4	1	5
Completed	1 (1.0)	1 (1.0)	2 (1.0)
Discontinued	3 (3.1)	0	3 (1.5)
DAI-10 total score at Week 28 : 0			
n	6	9	15
Completed	4 (4.1)	3 (2.9)	7 (3.5)
Discontinued	2 (2.1)	6 (5.8)	8 (4.0)
DAI-10 total score at Week 28 : 2			
n	14	11	25
Completed	12 (12.4)	7 (6.8)	19 (9.5)

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Discontinued	2 (2.1)	4 (3.9)	6 (3.0)
DAI-10 total score at Week 28 : 4			
n	8	6	14
Completed	4 (4.1)	3 (2.9)	7 (3.5)
Discontinued	4 (4.1)	3 (2.9)	7 (3.5)
DAI-10 total score at Week 28 : 6			
n	10	16	26
Completed	7 (7.2)	14 (13.6)	21 (10.5)
Discontinued	3 (3.1)	2 (1.9)	5 (2.5)
DAI-10 total score at Week 28 : 8			
n	19	20	39
Completed	18 (18.6)	14 (13.6)	32 (16.0)
Discontinued	1 (1.0)	6 (5.8)	7 (3.5)
DAI-10 total score at Week 28 : 10			
n	12	19	31
Completed	11 (11.3)	16 (15.5)	27 (13.5)
Discontinued	1 (1.0)	3 (2.9)	4 (2.0)

表 2.7.3.6-55　DAI-10 合計スコア変化量別のロナセンテープ貼付期間
（40 試験：ロナセンテープ貼付期）

安全性解析対象集団

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -20			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -18			
Duration of exposure (days)			
n	0	1	1
Mean (SD)	. (.)	160 (.)	160 (.)
Median	.	.	.
Min, Max	., .	., .	., .

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -16			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -14			
Duration of exposure (days)			
n	1	0	1
Mean (SD)	54 (.)	. (.)	54 (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -12			
Duration of exposure (days)			
n	1	3	4
Mean (SD)	252 (.)	146.0 (71.34)	172.5 (78.75)
Median	.	123.0	174.5
Min, Max	., .	89, 226	89, 252
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -10			
Duration of exposure (days)			
n	3	4	7
Mean (SD)	152.7 (102.14)	183.8 (191.99)	170.4 (148.94)
Median	196.0	185.5	196.0
Min, Max	36, 226	14, 350	14, 350
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -8			
Duration of exposure (days)			
n	4	5	9
Mean (SD)	61.8 (29.50)	300.6 (149.74)	194.4 (165.48)
Median	63.5	367.0	93.0
Min, Max	27, 93	33, 375	27, 375
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -6			
Duration of exposure (days)			
n	4	4	8

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Mean (SD)	242.8 (160.79)	197.3 (188.19)	220.0 (163.86)
Median	286.0	205.0	282.5
Min, Max	28, 371	14, 365	14, 371
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -4			
Duration of exposure (days)			
n	15	12	27
Mean (SD)	221.2 (159.75)	247.1 (126.23)	232.7 (143.72)
Median	357.0	292.0	315.0
Min, Max	2, 365	42, 364	2, 365
Change from baseline to Week 52 (LOCF) in DAI-10 total score : -2			
Duration of exposure (days)			
n	20	9	29
Mean (SD)	251.4 (157.04)	203.1 (133.14)	236.4 (149.39)
Median	355.5	195.0	350.0
Min, Max	7, 366	28, 367	7, 367
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 0			
Duration of exposure (days)			
n	22	29	51
Mean (SD)	265.2 (141.93)	248.2 (144.87)	255.5 (142.43)
Median	350.5	355.0	351.0
Min, Max	4, 371	4, 378	4, 378
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 2			
Duration of exposure (days)			
n	18	19	37
Mean (SD)	293.0 (133.90)	270.5 (138.95)	281.4 (135.10)
Median	364.0	357.0	357.0
Min, Max	10, 368	18, 377	10, 377
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 4			
Duration of exposure (days)			
n	5	8	13
Mean (SD)	326.6 (83.17)	305.8 (98.18)	313.8 (89.67)
Median	364.0	352.0	357.0
Min, Max	178, 368	128, 368	128, 368

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 6			
Duration of exposure (days)			
n	4	5	9
Mean (SD)	273.0 (177.36)	341.4 (51.02)	311.0 (119.99)
Median	360.5	357.0	357.0
Min, Max	7, 364	251, 371	7, 371
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 8			
Duration of exposure (days)			
n	0	4	4
Mean (SD)	. (.)	337.8 (37.62)	337.8 (37.62)
Median	.	352.5	352.5
Min, Max	., .	282, 364	282, 364
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 10			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 12			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 14			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 16			
Duration of exposure (days)			
n	0	0	0

	Cohort 1 (N = 97)	Cohort 2 (N = 103)	Overall (N = 200)
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 18			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .
Change from baseline to Week 52 (LOCF) in DAI-10 total score : 20			
Duration of exposure (days)			
n	0	0	0
Mean (SD)	. (.)	. (.)	. (.)
Median	.	.	.
Min, Max	., .	., .	., .

Duration of exposure (days) = the last application date - first application date + 1.