

Effects of Long-Term Treatment With TV-46000 on Symptom Improvement Over Time in Stabilized Patients With Schizophrenia

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SUPPLEMENTAL MATERIAL

Supplemental Table 1 SHINE demographics and baseline disease characteristics by patient-source cohort (ITT Population)

Demographic variables		De novo cohort n=106	Placebo rollover cohort ^a n=53	TV-46000 rollover cohort n=172
Age, years, median (range)		49.5 (20–64)	54.0 (19–67)	55.0 (21–67)
Age categorization, n (%), years	18–30	6 (6)	3 (6)	9 (5)
	>30–45	31 (29)	6 (11)	30 (17)
	>45–65	69 (65)	42 (79)	127 (74)
	>65 ^b	0	2 (4)	6 (3)
Male, n (%)		84 (79)	27 (51)	103 (60)
Race, n (%)	Black or African American	60 (57)	31 (58)	87 (51)
	White	43 (41)	20 (38)	82 (48)
	Asian or Pacific Islander	1 (<1)	1 (2)	2 (1)
	Other	0	1 (2)	1 (<1)
	Not reported	2 (2)	0	0
Disease length, years, mean (SD)		18.6 (11.69)	20.8 (11.83)	23.0 (12.39)
Time since the most recent relapse, months, mean (SD)		10.5 (6.18)	25.7 (9.06)	26.3 (7.66)
PANSS scores at screening, mean (SE) ^c	PANSS total score	71.1 (1.14)	–	–
	Positive symptoms	18.5 (0.45)	–	–
	Negative symptoms	18.0 (0.43)	–	–
	General psychopathology	34.5 (0.63)	–	–
CGI-S score at screening, mean (SE) ^c		3.9 (0.06)	–	–

^aTwo additional patients were randomized to the placebo rollover cohort but not treated^bPatients in the rollover cohorts who aged beyond 64 years during RISE were eligible to continue treatment in SHINE^cCalculated for de novo cohort only, n (TV-46000 q1m)=54, n (TV-46000 q2m)=52

– not applicable, CGI-S Clinical Global Impressions –Severity, ITT intent-to-treat, PANSS Positive and Negative Syndrome Scale, q1m once monthly, q2m every 2 months, SD standard deviation, SE standard error

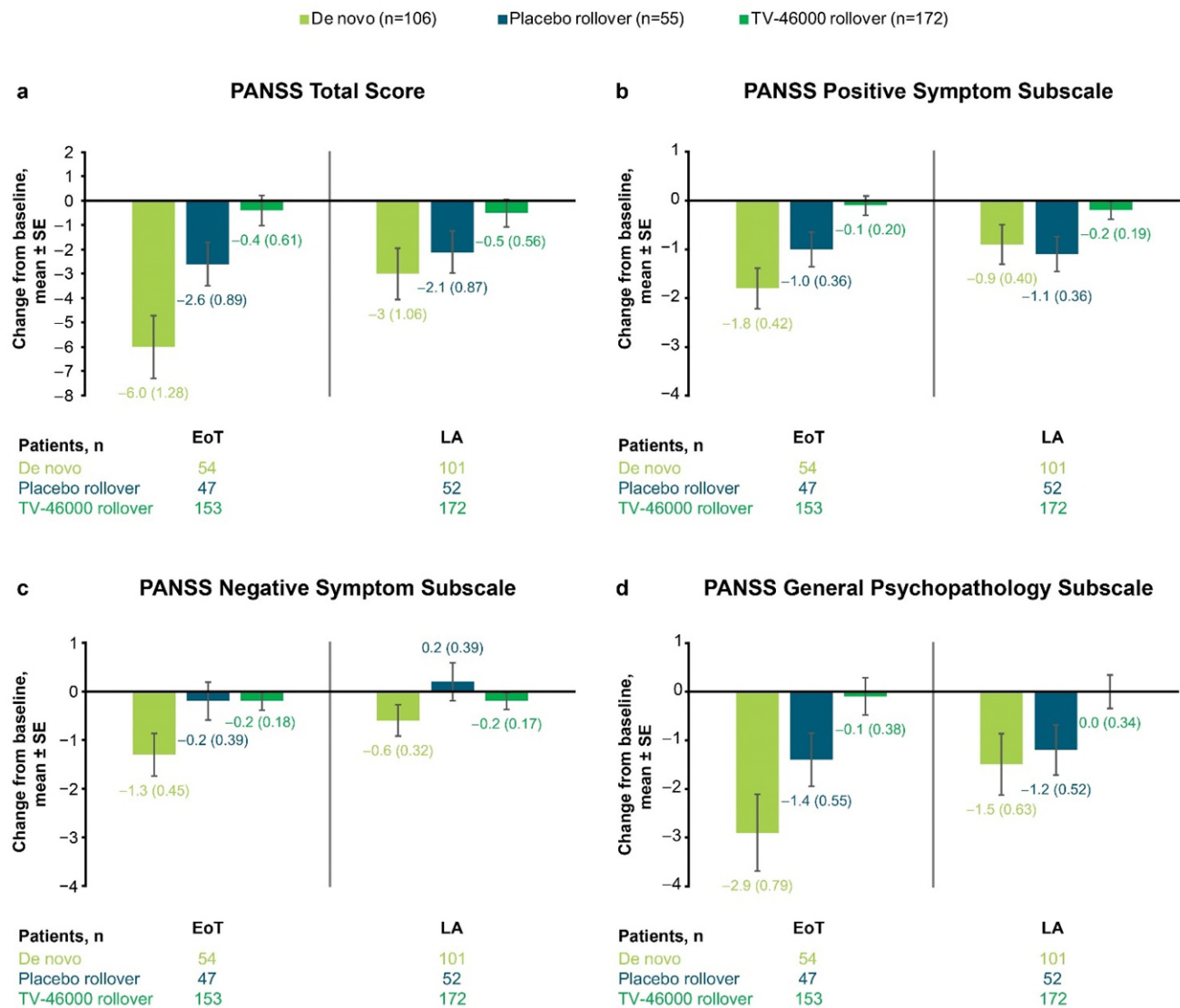
Supplemental Table 2 Mean change from screening to baseline for PANSS total and subscale scores after stabilization on oral risperidone

	Placebo ^a		TV-46000 q1m ^a		TV-46000 q2m ^a	
PANSS Score, mean (SE)	Screening	Randomization/ Baseline	Screening	Randomization/ Baseline	Screening	Randomization/ Baseline
	RISE					
PANSS total score	69.4 (0.92)	61.0 (0.78)	71.1 (0.81)	61.5 (0.71)	71.2 (0.84)	61.4 (0.77)
Positive symptoms	17.6 (0.30)	14.7 (0.26)	17.8 (0.28)	14.6 (0.24)	18.0 (0.29)	14.6 (0.22)
Negative symptoms	18.3 (0.37)	16.7 (0.37)	18.5 (0.35)	16.9 (0.33)	18.7 (0.34)	17.0 (0.35)
General psychopathology	33.5 (0.51)	29.6 (0.41)	34.8 (0.46)	29.9 (0.37)	34.5 (0.47)	29.8 (0.43)
	SHINE (De novo cohort)					
PANSS total score	–	–	72.0 (1.63)	59.9 (1.22)	70.1 (1.61)	58.9 (1.22)
Positive symptoms	–	–	18.6 (0.60)	13.6 (0.36)	18.4 (0.69)	13.6 (0.43)
Negative symptoms	–	–	18.2 (0.57)	15.7 (0.58)	17.8 (0.64)	16.0 (0.56)
General psychopathology	–	–	35.1 (0.94)	30.6 (0.75)	33.9 (0.82)	29.3 (0.69)

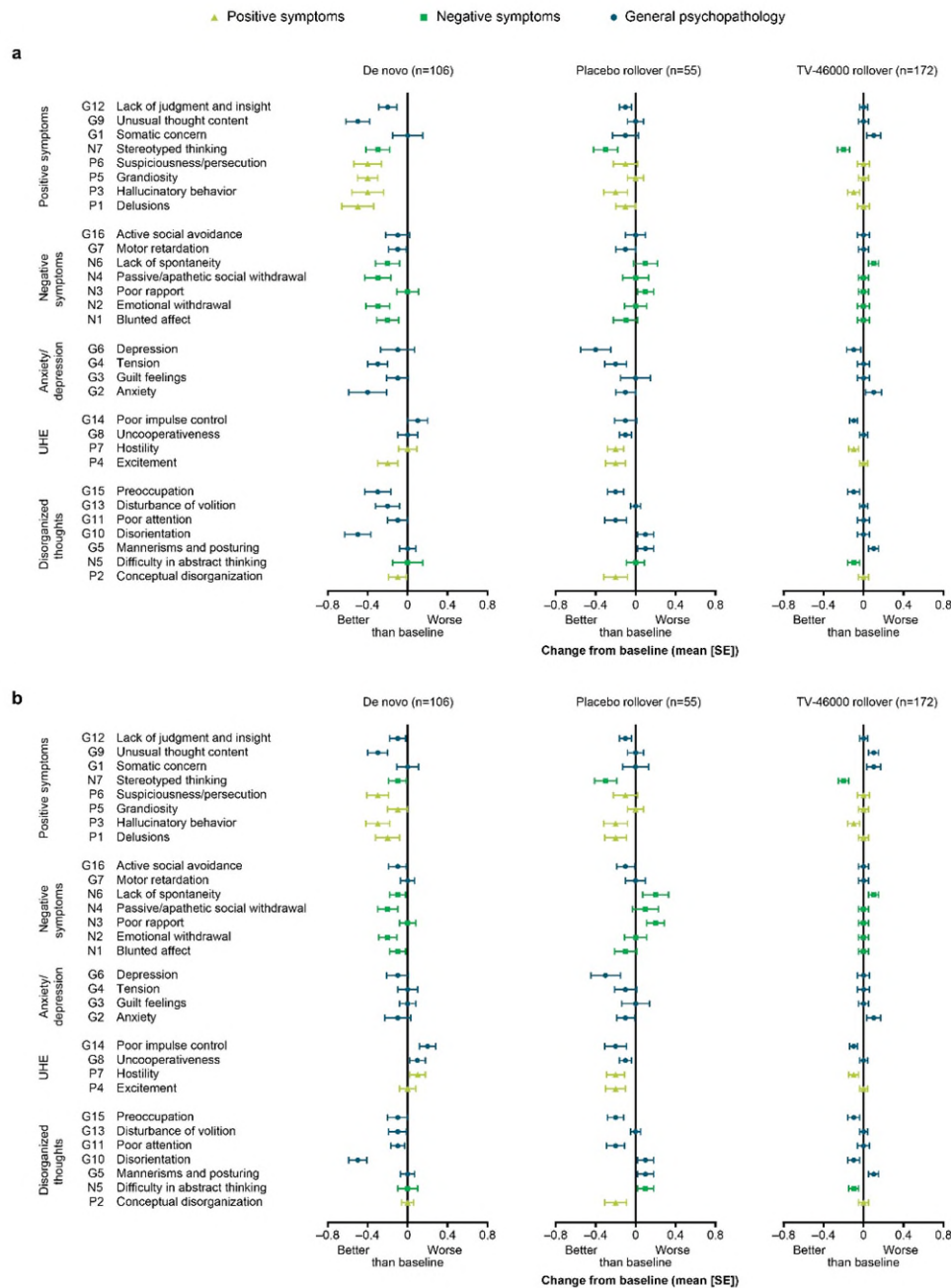
^aTreatment group assigned to patients at baseline/randomization. For the stabilization phase (stage 1) all patients were treated with oral risperidone

– not applicable, PANSS Positive and Negative Syndrome Scale, q1m once monthly, q2m every 2 months, SE standard error

Supplemental Fig. 1 Mean change from baseline to EoT and LA for PANSS total and subscale scores (SHINE, by patient-source cohort) (a) PANSS total score (b) PANSS positive symptoms subscale (c) PANSS negative symptoms subscale (d) PANSS general psychopathology subscale. *EoT* end of treatment, *LA* last assessment, *LS* least squares, *PANSS* Positive and Negative Syndrome Scale, *SE* standard error



Supplemental Fig. 2 Mean change from baseline to EoT and LA for PANSS item scores, categorized by Marder Factors^a (SHINE, by patient-source cohort) (a) SHINE: Mean change from baseline to EoT (b) SHINE: Mean change from baseline to LA. ^aFactors per Marder et al. [46]. Each item's assignment in the original PANSS structure is noted along the y-axis (*P* positive symptoms, *N* negative symptoms, *G* general psychopathology). *EoT* end of treatment, *LA* last assessment, *LS* least squares, *PANSS* Positive and Negative Syndrome Scale, *SE* standard error, *UHE* Uncontrolled hostility/excitement



Supplemental Fig. 3 Clinical Global Impressions—Improvement by study visit (SHINE, by patient-source cohort^a). ^aRollover patients did not contribute an entire year of exposure to the study. *EoT* end of treatment, *LA* last assessment

