

SUPPLEMENTARY TABLE S2. SUMMARY OF EFFICACY FINDINGS, FULL ANALYSIS SET

	Placebo	SHP465 MAS
ADHD-RS-IV total score		
Mean ± SD score at baseline*	40.0 ± 6.96	39.0 ± 6.95
Mean ± SD score at week 4 [†]	28.2 ± 13.71	17.3 ± 11.78
LS mean (95% CI) change at week 4 [†]	-10.8 (-13.0, -8.5)	-20.7 (-22.9, -18.5)
LS mean (95% CI) treatment difference at week 4 [†]		-9.9 (-13.0, -6.8)
<i>p</i> -Value (degrees of freedom, <i>t</i> -statistic) [§]		<0.001 (241, -6.23)
Effect size ^e		0.80
ADHD-RS-IV hyperactivity/impulsivity subscale score		
Mean ± SD score at baseline*	17.9 ± 5.52	17.0 ± 5.86
Mean ± SD score at week 4 [†]	12.8 ± 7.71	7.1 ± 6.24
LS mean (95% CI) change at week 4 [†]	-4.5 (-5.6, -3.4)	-9.5 (-10.6, -8.4)
LS mean (95% CI) treatment difference at week 4 [†]		-4.9 (-6.5, -3.4)
Nominal <i>p</i> -value (degrees of freedom, <i>t</i> -statistic) [§]		<0.001 (241, -6.25)
Effect size ^e		0.81
ADHD-RS-IV inattentiveness subscale score		
Mean ± SD score at baseline*	22.1 ± 3.57	22.0 ± 3.20
Mean ± SD score at week 4 [†]	15.4 ± 7.33	10.2 ± 6.52
LS mean (95% CI) change at week 4 [†]	-6.2 (-7.5, -5.0)	-11.2 (-12.5, -10.0)
LS mean (95% CI) treatment difference at week 4 [†]		-5.0 (-6.7, -3.2)
Nominal <i>p</i> -value (degrees of freedom, <i>t</i> -statistic) [§]		<0.001 (239, -5.62)
Effect size ^e		0.72
CGI-I score		
Mean ± SD score at week 1*	3.5 ± 0.82	2.9 ± 1.08
Mean ± SD score at week 4 [‡]	2.9 ± 1.20	2.1 ± 1.13
LS mean (95% CI) at week 4 [‡]	3.0 (2.8, 3.2)	2.2 (2.0, 2.4)
LS mean (95% CI) treatment difference at week 4 [‡]		-0.8 (-1.1, -0.5)
<i>p</i> -Value (degrees of freedom, <i>t</i> -statistic) [§]		<0.001 (242, -5.10)
Effect size ^e		0.65
CGI-I*		
Improved [‡] at final on-treatment assessment, <i>n</i> (%)	47 (36.4)	77 (60.2)
Nominal <i>p</i> -value (degrees of freedom, CMH statistic)		<0.001 (1, 12.7799)

*Based on *n* = 129 for placebo and *n* = 128 for SHP465 MAS.

[†]Based on *n* = 117 for placebo and *n* = 113 for SHP465 MAS.

[‡]Based on *n* = 117 for placebo and *n* = 112 for SHP465 MAS.

[§]Based on LS mean treatment difference from placebo; mixed-effects model for repeated measures analysis included treatment group, visit, age group, interaction of the treatment group × visit as factors, baseline score as a covariate, and an adjustment for the interaction of the baseline score × visit.

^eThe difference in LS means divided by the estimated standard deviation from the unstructured covariance matrix.

[‡]Improved categorized as scores of 1 (very much improved) and 2 (much improved).

^{||}Based on the Cochran-Mantel-Haenszel test stratified by age group and baseline CGI-Severity score.

ADHD, attention-deficit/hyperactivity disorder; ADHD-RS-IV, ADHD Rating Scale IV; CGI-I, Clinical Global Impressions-Improvement; CI, confidence interval; CMH, Cochran-Mantel-Haenszel; FAS, full analysis set; LS, least squares; MAS, mixed amphetamine salts; SD, standard deviation.