

CONFIDENTIAL: CAMP PRIMARY OUTCOME RESULTS

Table 2 (supplement). Outcome Measures of Effectiveness in the Efficacy Evaluable Population – by incoming study medication

	<i>Olanzapine</i>						<i>Quetiapine</i>						<i>Risperidone</i>					
	<i>Switch (N=29)</i>		<i>Stay (N=35)</i>		<i>Diff</i>	<i>95% CI</i>	<i>Switch (N=23)</i>		<i>Stay (N=28)</i>		<i>Diff</i>	<i>95% CI</i>	<i>Switch (N=37)</i>		<i>Stay (N=35)</i>		<i>Diff</i>	<i>95% CI</i>
	<i>Mean</i>	<i>SE</i>	<i>Mean</i>	<i>SE</i>			<i>Mean</i>	<i>SE</i>	<i>Mean</i>	<i>SE</i>			<i>Mean</i>	<i>SE</i>	<i>Mean</i>	<i>SE</i>		
Primary Outcome																		
Change in nonHDL	-29.6	5.01	-15.8	3.98	13.7	(1.4,26.1)	-15.5	5.72	-11.8	4.82	3.7	(-10.7,18.0)	-15.6	4.09	-5.8	4.16	9.9	(-1.3,21.0)
Other Secondary Outcomes																		
Metabolic Outcomes																		
Change in HDL Cholesterol	0.9	1.38	0.3	1.08	-0.5	(-4.0,2.9)	-0.4	1.55	-0.1	1.32	0.4	(-3.6,4.4)	1.1	1.12	-0.7	1.14	-1.8	(-4.9,1.4)
Change in weight (kg)	-4.2	0.88	-1.0	0.73	3.2	(1.0,5.4)	-2.2	0.97	-0.6	0.85	1.6	(-0.9,4.1)	-4.0	0.72	-0.8	0.74	3.3	(1.2,5.3)
Change in BMI (kg/m ²)	-1.5	0.31	-0.3	0.26	1.1	(0.4,1.9)	-0.7	0.34	-0.1	0.30	0.6	(-0.3,1.5)	-1.5	0.25	-0.3	0.26	1.2	(0.5,1.9)
Change in Total Cholesterol	-28.4	5.16	-15.3	4.09	13.1	(0.4,25.7)	-16.2	5.90	-11.6	4.96	4.6	(-10.2,19.3)	-15.0	4.20	-6.6	4.29	8.5	(-2.9,19.9)
Change in LDL Cholesterol	-26.1	4.74	-15.2	3.75	10.9	(-0.6,22.5)	-10.7	5.36	-13.3	4.78	-2.6	(-16.4,11.2)	-10.1	3.85	-9.7	4.12	0.4	(-10.3,11.1)
Change in Triglycerides	-17.9	14.43	-0.6	11.38	17.3	(-18.6,53.3)	-29.7	16.49	12.6	13.87	42.3	(0.5,84.0)	-31.4	11.66	7.3	11.89	38.6	(6.1,71.2)
Change in TG/HDL ratio	-0.6	0.45	-0.1	0.35	0.5	(-0.6,1.6)	-1.0	0.51	0.4	0.43	1.4	(0.1,2.7)	-0.9	0.36	0.2	0.37	1.1	(0.1,2.1)
Change in HBA1c	-0.0	0.05	-0.0	0.04	0.0	(-0.1,0.1)	0.1	0.06	0.1	0.05	-0.0	(-0.2,0.1)	0.0	0.04	0.1	0.04	0.1	(-0.0,0.2)
Change in fasting glucose	2.6	2.58	4.5	1.95	2.0	(-4.4,8.3)	1.6	2.94	7.0	2.44	5.4	(-2.0,12.8)	-1.7	2.05	1.1	2.08	2.8	(-2.9,8.5)
Change in fasting insulin	6.2	4.68	2.0	3.53	-4.2	(-15.7,7.4)	2.7	5.32	10.4	4.44	7.6	(-6.0,21.2)	-3.6	3.71	7.7	3.87	11.3	(0.8,21.9)
Change in 2-hour glucose	-7.5	7.15	-5.6	5.63	1.9	(-15.5,19.3)	-9.9	8.27	-3.3	6.84	6.7	(-13.8,27.1)	-14.3	5.81	-10.2	5.94	4.2	(-11.5,19.9)
Change in 2-hour insulin	-21.3	13.59	-12.9	10.61	8.4	(-25.2,42.0)	-28.7	15.71	-19.9	12.98	8.8	(-30.6,48.2)	-42.3	10.96	3.5	11.20	45.8	(15.4,76.2)
Change in C-reactive protein	-3.8	2.31	-0.9	1.88	2.9	(-2.9,8.8)	-1.0	2.59	7.3	2.19	8.2	(1.7,14.8)	-1.3	1.88	-1.3	1.92	0.1	(-5.2,5.3)
Measures of Clinical Status																		
Change in PANSS Total	-6.5	2.41	-5.9	1.97	0.6	(-5.4,6.6)	-7.3	2.84	0.8	2.33	8.1	(1.0,15.1)	-3.2	2.03	-5.9	2.04	-2.7	(-8.2,2.7)
Change in CGI-Severity Score	0.1	0.15	-0.2	0.12	-0.3	(-0.6,0.1)	-0.5	0.17	-0.2	0.14	0.3	(-0.1,0.7)	-0.3	0.12	-0.3	0.13	-0.0	(-0.3,0.3)
Chg in SF-12 mntl health score	-2.9	2.48	2.3	1.84	5.3	(-0.9,11.4)	-0.4	2.69	-2.3	2.15	-2.0	(-8.7,4.8)	2.6	1.95	-0.4	1.91	-3.0	(-8.4,2.4)
Chg in SF-12 phys health score	-1.1	2.00	-1.1	1.46	-0.0	(-4.9,4.9)	2.7	2.15	-4.3	1.74	-7.0	(-12.4,-1.6)	4.4	1.57	0.0	1.54	-4.4	(-8.8,-0.1)
Chg in IWQoL Total	-10.6	4.51	-7.3	3.35	3.2	(-7.8,14.2)	-15.8	4.93	0.3	3.88	16.1	(4.1,28.1)	-15.5	3.55	-5.1	3.52	10.4	(0.6,20.2)

For the following outcomes of change in nonHDL, HDL, weight, BMI, Total Cholesterol, LDL, Triglycerides, TG/HDL ratio, HBA1c, fasting glucose, fasting insulin, 2-hour glucose, 2-hour insulin, C-reactive protein, PANSS Total, and CGI-S severity score, a linear mixed model that appropriately accounts for correlations among clinic visits associated with a single patient and for randomly missing data is used to test for the difference in least square means in change from baseline between stay and switch at the 24-week visit. Model effects include main effects corresponding to incoming medication, baseline, visit and treatment, as well as treatment by visit, treatment by incoming medication and treatment by incoming study medication by visit interaction terms.

For the comparison of the outcomes of change in SF-12 mental health score, SF-12 physical health score, and IWQoL Total, which are measured at the last follow-up only, are from a mixed model with fixed effects incoming medication, baseline, treatment, a treatment by incoming medication interaction term and random effect pooled site.

Least squares means and standard errors from the mixed model are presented.