

CONFIDENTIAL: CAMP PRIMARY OUTCOME RESULTS
Table 3 (supplement). CAMP General Safety Summary

	Olanzapine						Quetiapine						Risperidone					
	Total (N=74)		Switch (N=38)		Stay (N=36)		Total (N=59)		Switch (N=29)		Stay (N=30)		Total (N=80)		Switch (N=40)		Stay (N=40)	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Protocol-specified efficacy failure	10	13.5	7	18.4	3	8.3	17	28.8	8	27.6	9	30.0	13	16.3	7	17.5	6	15.0
Early discontinuation of protocol-specified treatment	25	33.8	21	55.3	4	11.1	29	49.2	17	58.6	12	40.0	26	32.5	13	32.5	13	32.5
Discontinuation of study antipsychotic due to any cause	23	31.1	19	50.0	4	11.1	28	47.5	16	55.2	12	40.0	22	27.5	12	30.0	10	25.0
Discontinuation of study antipsychotic due to inefficacy	14	18.9	14	36.8	0	0.0	4	6.8	2	6.9	2	6.7	3	3.8	2	5.0	1	2.5
Discontinuation of study antipsychotic due to intolerability	1	1.4	1	2.6	0	0.0	9	15.3	5	17.2	4	13.3	3	3.8	1	2.5	2	5.0
Dropped out - no information available	5	6.8	3	7.9	2	5.6	8	13.6	6	20.7	2	6.7	10	12.5	6	15.0	4	10.0
Dropped out due to withdrawn consent	2	2.7	0	0.0	2	5.6	7	11.9	3	10.3	4	13.3	5	6.3	2	5.0	3	7.5
Discontinuation of study antipsychotic due to other reasons	1	1.4	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.3	1	2.5	0	0.0
Participants with any SAE*	7	9.5	7	18.4	0	0.0	12	20.3	8	27.6	4	13.3	9	11.3	3	7.5	6	15.0
Participants with any psychiatric hospitalization	3	4.1	3	7.9	0	0.0	5	8.5	3	10.3	2	6.7	5	6.3	2	5.0	3	7.5
Deaths	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Participants with any AE ⁺	49	66.2	28	73.7	21	58.3	49	83.1	24	82.8	25	83.3	62	77.5	29	72.5	33	82.5
Participants with at least one AE from Systematic Inquiry ⁺	48	64.9	27	71.1	21	58.3	48	81.4	23	79.3	25	83.3	58	72.5	27	67.5	31	77.5
Insomnia	18	24.3	11	28.9	7	19.4	29	49.2	17	58.6	12	40.0	26	32.5	16	40.0	10	25.0
Sleepiness	17	23.0	9	23.7	8	22.2	20	33.9	7	24.1	13	43.3	25	31.3	11	27.5	14	35.0
Dry mouth	13	17.6	6	15.8	7	19.4	24	40.7	11	37.9	13	43.3	23	28.8	7	17.5	16	40.0
Akathisia/activation	11	14.9	8	21.1	3	8.3	23	39.0	10	34.5	13	43.3	21	26.3	11	27.5	10	25.0
Problems with sex drive	12	16.2	6	15.8	6	16.7	21	35.6	10	34.5	11	36.7	17	21.3	8	20.0	9	22.5
Increased appetite	14	18.9	8	21.1	6	16.7	15	25.4	6	20.7	9	30.0	15	18.8	4	10.0	11	27.5
Weight gain	14	18.9	7	18.4	7	19.4	18	30.5	9	31.0	9	30.0	9	11.3	4	10.0	5	12.5
Constipation	12	16.2	4	10.5	8	22.2	14	23.7	8	27.6	6	20.0	14	17.5	8	20.0	6	15.0

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	<i>Total (N=74)</i>		<i>Switch (N=38)</i>		<i>Stay (N=36)</i>		<i>Total (N=59)</i>		<i>Switch (N=29)</i>		<i>Stay (N=30)</i>		<i>Total (N=80)</i>		<i>Switch (N=40)</i>		<i>Stay (N=40)</i>	
	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>	<i>N</i>	<i>%</i>
Akinesia	9	12.2	5	13.2	4	11.1	12	20.3	4	13.8	8	26.7	18	22.5	5	12.5	13	32.5
Problems with sexual orgasm	8	10.8	6	15.8	2	5.6	13	22.0	7	24.1	6	20.0	18	22.5	7	17.5	11	27.5
Problems with sexual arousal	9	12.2	7	18.4	2	5.6	13	22.0	6	20.7	7	23.3	16	20.0	7	17.5	9	22.5
Hypersomnia	11	14.9	6	15.8	5	13.9	15	25.4	7	24.1	8	26.7	11	13.8	3	7.5	8	20.0
Orthostatic faintness	8	10.8	4	10.5	4	11.1	13	22.0	9	31.0	4	13.3	16	20.0	6	15.0	10	25.0
Nausea	11	14.9	5	13.2	6	16.7	9	15.3	4	13.8	5	16.7	10	12.5	3	7.5	7	17.5
Incontinence/nocturia	4	5.4	1	2.6	3	8.3	9	15.3	6	20.7	3	10.0	9	11.3	2	5.0	7	17.5
Skin rash	5	6.8			5	13.9	10	16.9	6	20.7	4	13.3	5	6.3	2	5.0	3	7.5
Menstrual irregularities	3	4.1	3	7.9			6	10.2	4	13.8	2	6.7	7	8.8	3	7.5	4	10.0
Sialorrhea	8	10.8	4	10.5	4	11.1	5	8.5	4	13.8	1	3.3	2	2.5			2	5.0
Urinary hesitancy	2	2.7			2	5.6	5	8.5	3	10.3	2	6.7	2	2.5	2	5.0		
Gynecomastia/galactorrhea	1	1.4			1	2.8	2	3.4	1	3.4	1	3.3	3	3.8	1	2.5	2	5.0

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Uses intent-to-treat population.

'Protocol-specified efficacy failure' are those participants who had either a psychiatric hospitalization, a 25 percent increase from baseline on the Positive and Negative Syndrome Scale (PANSS) (or a 10 point increase for individuals with a baseline total score of 40 or less), or substantial clinical deterioration on the Clinical Global Impressions-Change (CGI-C) Scale (i.e., 6- much worse or 7- very much worse).

'Early discontinuation of protocol-specified treatment' include both early treatment discontinuations AND participants who started/stopped/changed dose of a disallowed medication (Lipid Lowering Agent or Mood Stabilizer).

'Discontinuation of study antipsychotic due to any cause' are those participants who answered 'No' to the question 1 on the RTDA form 'Did patient complete 24 weeks on the assigned treatment?'

'Discontinuation of study antipsychotic due to inefficacy' are the participants who mentioned study treatment was stopped due to Positive Symptoms, Negative Symptoms, Mood Symptoms or Other Inefficacy/Inadequate Therapeutic Effect (question 3, values '01' to '04' on RTDA form).

'Discontinuation of study antipsychotic due to intolerability' are the participants who mentioned study treatment was stopped due to Weight, Lipids, Glucose, EPS, TD, Akathisia/activation, Sedation, Insomnia, Agitation, Sexual Side effects, Nausea, Other unacceptable side effects (question 3, values '05' to '16' on RTDA form).

'Dropped out due to withdrawn consent' are the participants who mentioned study treatment was stopped due to the patient not seeing need for treatment or patient no longer wanting to participate in the study (question 3, values '17' and '18' on RTDA form).

'Discontinuation of study antipsychotic due to other reasons' are participants where study treatment was stopped due to administrative reasons (question 3, value '21' on RTDA form).

'Death' comes from question 3, value '20' on the RTDA form.

* Only events after randomization are included here.

+ Includes 'moderate' to 'severe' adverse events recorded post-baseline.

AE includes Adverse Events both from systematic inquiry and general inquiry.