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Table 4a (Supplemental): Changes in Laboratory Measures, Weight, and Extrapyramidal Symptom Scales from Randomization to 24-Week Endpoint (in Standard International Units)

Measurement	Therapy	Dose	Baseline at Randomization			Randomization-to-Endpoint Change		Significance Within Group	Significance Across Groups	Significance Overall	Significance vs. Olz LAI 45 mg/4wk
			N	Mean	SD	Mean	SD				
Fasting glucose (mmol/L)	Olz LAI	45 mg/4wk (ref)	111	5.42	1.50	-0.01	0.75	0.93	0.38	-	
		150 mg/2wk (low)	110	5.41	0.99	+0.14	1.36	0.28		0.16	
		405 mg/4wk (med)	257	5.54	1.68	+0.16	1.29	0.05		0.09	
		300 mg/2wk (high)	114	5.53	1.84	+0.20	1.15	0.07		0.34	
	Oral olz	10, 15, 20 mg/day	285	5.36	1.07	+0.07	0.90	0.20		0.53	
Cholesterol (mmol/L)	Olz LAI	45 mg/4wk	115	5.44	1.24	-0.37	0.80	<0.001	<0.01	-	
		150 mg/2wk	117	5.35	1.22	-0.11	0.72	0.10		<0.01	
		405 mg/4wk	276	5.20	1.18	-0.10	0.73	0.02		<0.01	
		300 mg/2wk	126	5.30	1.11	-0.02	0.81	0.80		<0.001	
	Oral olz	10, 15, 20 mg/day	305	5.22	1.10	-0.14	0.80	<0.01		<0.01	
LDL cholesterol (mmol/L)	Olz LAI	45 mg/4wk	109	3.46	1.05	-0.32	0.68	<0.001	0.02	-	
		150 mg/2wk	114	3.33	1.01	-0.08	0.65	0.19		0.01	
		405 mg/4wk	264	3.20	1.04	-0.09	0.63	0.02		<0.01	
		300 mg/2wk	123	3.23	0.88	-0.01	0.76	0.93		<0.01	
	Oral olz	10, 15, 20 mg/day	297	3.23	0.99	-0.16	0.73	<0.001		<0.05	
HDL cholesterol (mmol/L)	Olz LAI	45 mg/4wk	114	1.14	0.33	+0.02	0.22	0.35	0.12	-	
		150 mg/2wk	117	1.17	0.35	+0.01	0.23	0.72		0.52	
		405 mg/4wk	272	1.12	0.32	-0.01	0.24	0.69		0.15	
		300 mg/2wk	125	1.16	0.32	-0.05	0.24	0.01		0.01	
	Oral olz	10, 15, 20 mg/day	305	1.13	0.33	-0.01	0.22	0.38		0.11	
Triglycerides (mmol/L)	Olz LAI	45 mg/4wk	115	1.91	1.37	-0.14	1.12	0.17	0.20	-	
		150 mg/2wk	117	2.05	2.28	-0.11	1.76	0.49		0.40	
		405 mg/4wk	276	2.02	1.42	-0.00	1.23	0.99		0.10	
		300 mg/2wk	126	1.99	1.24	+0.01	1.13	0.95		0.23	
	Oral olz	10, 15, 20 mg/day	305	1.92	1.20	+0.09	1.20	0.19		0.02	

Prolactin (ng/mL)	Olz LAI	45 mg/4wk	104	21.45	16.15	-7.53	15.24	<0.001	<0.01	-
		150 mg/2wk	109	21.78	15.86	-5.61	12.49	<0.001		0.48
		405 mg/4wk	259	22.59	23.19	-2.76	19.02	0.02		<0.001
		300 mg/2wk	115	24.62	25.99	+3.57 ^{a,b,c}	33.77	0.26		0.04
	Oral olz	10, 15, 20 mg/day	276	22.01	18.95	-1.79	18.59	0.11		0.02
Weight										
Weight (kg)	Olz LAI	45 mg/4wk	144	78.44	17.27	-0.95	4.09	<0.01	<0.001	-
		150 mg/2wk	140	78.40	16.49	+0.67	4.38	0.07		<0.001
		405 mg/4wk	315	77.80	15.73	+0.89	3.87	<0.001		<0.001
		300 mg/2wk	140	75.18	15.61	+1.70 ^a	4.14	<0.001		<0.001
	Oral olz	10, 15, 20 mg/day	322	76.95	15.91	+1.30	3.99	<0.001		<0.001
Extrapyramidal Symptom Scales										
Simpson-Angus Total	Olz LAI	45 mg/4wk	144	1.65	2.79	-0.35	2.20	0.06	0.64	-
		150 mg/2wk	139	1.01	1.89	-0.35	1.53	0.01		0.81
		405 mg/4wk	315	1.31	2.26	-0.28	1.67	<0.01		0.66
		300 mg/2wk	140	1.43	2.40	-0.43	1.78	0.01		0.81
	Oral olz	10, 15, 20 mg/day	322	1.23	2.44	-0.14	1.90	0.18		0.34
Barnes Global Score	Olz LAI	45 mg/4wk	144	0.21	0.51	-0.05	0.56	0.30	<0.01	-
		150 mg/2wk	139	0.19	0.53	0.00	0.50	1.00		0.45
		405 mg/4wk	315	0.20	0.48	+0.01	0.52	0.67		0.26
		300 mg/2wk	140	0.37	0.73	-0.18 ^{a,b,c}	0.73	<0.01		0.02
	Oral olz	10, 15, 20 mg/day	322	0.19	0.50	-0.03	0.41	0.17		0.74
Abnormal Involuntary Movement Scale Total	Olz LAI	45 mg/4wk	144	0.99	2.23	-0.14	1.54	0.28	0.02	-
		150 mg/2wk	139	0.50	1.36	-0.06	0.98	0.44		0.52
		405 mg/4wk	316	0.67	1.75	-0.04	1.37	0.62		0.41
		300 mg/2wk	140	1.04	1.92	-0.40 ^{a,b,c}	1.55	<0.01		0.04
	Oral olz	10, 15, 20 mg/day	322	0.71	1.80	-0.18	1.20	<0.01		0.68

Olz LAI = olanzapine long-acting injection; oral olz = oral olanzapine; ref = reference; med = medium. Within-group difference calculated by one sample t-test; pairwise treatment comparisons calculated using analysis of variance.

^a p<0.05 vs. Olz LAI 150 mg/2-weeks

^b p<0.05 vs. Olz LAI 405 mg/4-weeks

^c p<0.05 vs. oral olanzapine

Table 4b (Supplemental): Changes in Laboratory Measures, Weight, and Extrapyramidal Symptom Scales from Randomization to 24-Week Endpoint (in Conventional Units)

Measurement	Therapy	Dose	Baseline at Randomization			Randomization-to-Endpoint Change		Significance Within Group	Significance Across Groups	Significance vs. Olz LAI 45 mg/4wk Overall
			N	Mean	SD	Mean	SD			
Fasting glucose (mg/dL)	Olz LAI	45 mg/4wk (ref)	111	97.6	27.0	-0.2	13.5	0.93	0.38	-
		150 mg/2wk (low)	110	97.4	17.8	+2.5	24.5	0.28		0.16
		405 mg/4wk (med)	257	99.7	30.2	+2.9	23.2	0.05		0.09
		300 mg/2wk (high)	114	99.5	33.1	+3.6	20.7	0.07		0.34
	Oral olz	10, 15, 20 mg/day	285	96.5	19.3	+1.3	16.2	0.20		0.53
Cholesterol (mg/dL)	Olz LAI	45 mg/4wk	115	210.5	48.0	-14.3	31.0	<0.001	<0.01	-
		150 mg/2wk	117	207.0	47.2	-4.3	27.9	0.10		<0.01
		405 mg/4wk	276	201.2	45.7	-3.9	28.3	0.02		<0.01
		300 mg/2wk	126	205.1	43.0	-0.8	31.3	0.80		<0.001
	Oral olz	10, 15, 20 mg/day	305	202.0	42.6	-5.4	31.0	<0.01		<0.01
LDL cholesterol (mg/dL)	Olz LAI	45 mg/4wk	109	133.9	40.6	-12.4	26.3	<0.001	0.02	-
		150 mg/2wk	114	128.9	39.1	-3.1	25.2	0.19		0.01
		405 mg/4wk	264	123.8	40.2	-3.5	24.4	0.02		<0.01
		300 mg/2wk	123	125.0	34.1	-0.4	29.4	0.93		<0.01
	Oral olz	10, 15, 20 mg/day	297	125.0	38.3	-6.2	28.3	<0.001		<0.05
HDL cholesterol (mg/dL)	Olz LAI	45 mg/4wk	114	44.1	12.8	+0.8	8.5	0.35	0.12	-
		150 mg/2wk	117	45.3	13.5	+0.4	8.9	0.72		0.52
		405 mg/4wk	272	43.3	12.4	-0.4	9.3	0.69		0.15
		300 mg/2wk	125	44.9	12.4	-1.9	9.3	0.01		0.01
	Oral olz	10, 15, 20 mg/day	305	43.7	12.8	-0.4	8.5	0.38		0.11
Triglycerides (mg/dL)	Olz LAI	45 mg/4wk	115	169.2	121.4	-12.4	99.2	0.17	0.20	-
		150 mg/2wk	117	181.6	202.0	-9.7	155.9	0.49		0.40
		405 mg/4wk	276	179.0	125.8	-0.0	109.0	0.99		0.10
		300 mg/2wk	126	176.3	109.9	+0.9	100.1	0.95		0.23
	Oral olz	10, 15, 20 mg/day	305	170.1	106.3	+8.0	106.3	0.19		0.02

Prolactin (ng/mL)	Olz LAI	45 mg/4wk	104	21.45	16.15	-7.53	15.24	<0.001	<0.01	-
		150 mg/2wk	109	21.78	15.86	-5.61	12.49	<0.001		0.48
		405 mg/4wk	259	22.59	23.19	-2.76	19.02	0.02		<0.001
		300 mg/2wk	115	24.62	25.99	+3.57 ^{a,b,c}	33.77	0.26		0.04
	Oral olz	10, 15, 20 mg/day	276	22.01	18.95	-1.79	18.59	0.11		0.02
Weight										
Weight (kg)	Olz LAI	45 mg/4wk	144	78.44	17.27	-0.95	4.09	<0.01	<0.001	-
		150 mg/2wk	140	78.40	16.49	+0.67	4.38	0.07		<0.001
		405 mg/4wk	315	77.80	15.73	+0.89	3.87	<0.001		<0.001
		300 mg/2wk	140	75.18	15.61	+1.70 ^a	4.14	<0.001		<0.001
	Oral olz	10, 15, 20 mg/day	322	76.95	15.91	+1.30	3.99	<0.001		<0.001
Extrapyramidal Symptom Scales										
Simpson-Angus Total	Olz LAI	45 mg/4wk	144	1.65	2.79	-0.35	2.20	0.06	0.64	-
		150 mg/2wk	139	1.01	1.89	-0.35	1.53	0.01		0.81
		405 mg/4wk	315	1.31	2.26	-0.28	1.67	<0.01		0.66
		300 mg/2wk	140	1.43	2.40	-0.43	1.78	0.01		0.81
	Oral olz	10, 15, 20 mg/day	322	1.23	2.44	-0.14	1.90	0.18		0.34
Barnes Global Score	Olz LAI	45 mg/4wk	144	0.21	0.51	-0.05	0.56	0.30	<0.01	-
		150 mg/2wk	139	0.19	0.53	0.00	0.50	1.00		0.45
		405 mg/4wk	315	0.20	0.48	+0.01	0.52	0.67		0.26
		300 mg/2wk	140	0.37	0.73	-0.18 ^{a,b,c}	0.73	<0.01		0.02
	Oral olz	10, 15, 20 mg/day	322	0.19	0.50	-0.03	0.41	0.17		0.74
Abnormal Involuntary Movement Scale Total	Olz LAI	45 mg/4wk	144	0.99	2.23	-0.14	1.54	0.28	0.02	-
		150 mg/2wk	139	0.50	1.36	-0.06	0.98	0.44		0.52
		405 mg/4wk	316	0.67	1.75	-0.04	1.37	0.62		0.41
		300 mg/2wk	140	1.04	1.92	-0.40 ^{a,b,c}	1.55	<0.01		0.04
	Oral olz	10, 15, 20 mg/day	322	0.71	1.80	-0.18	1.20	<0.01		0.68

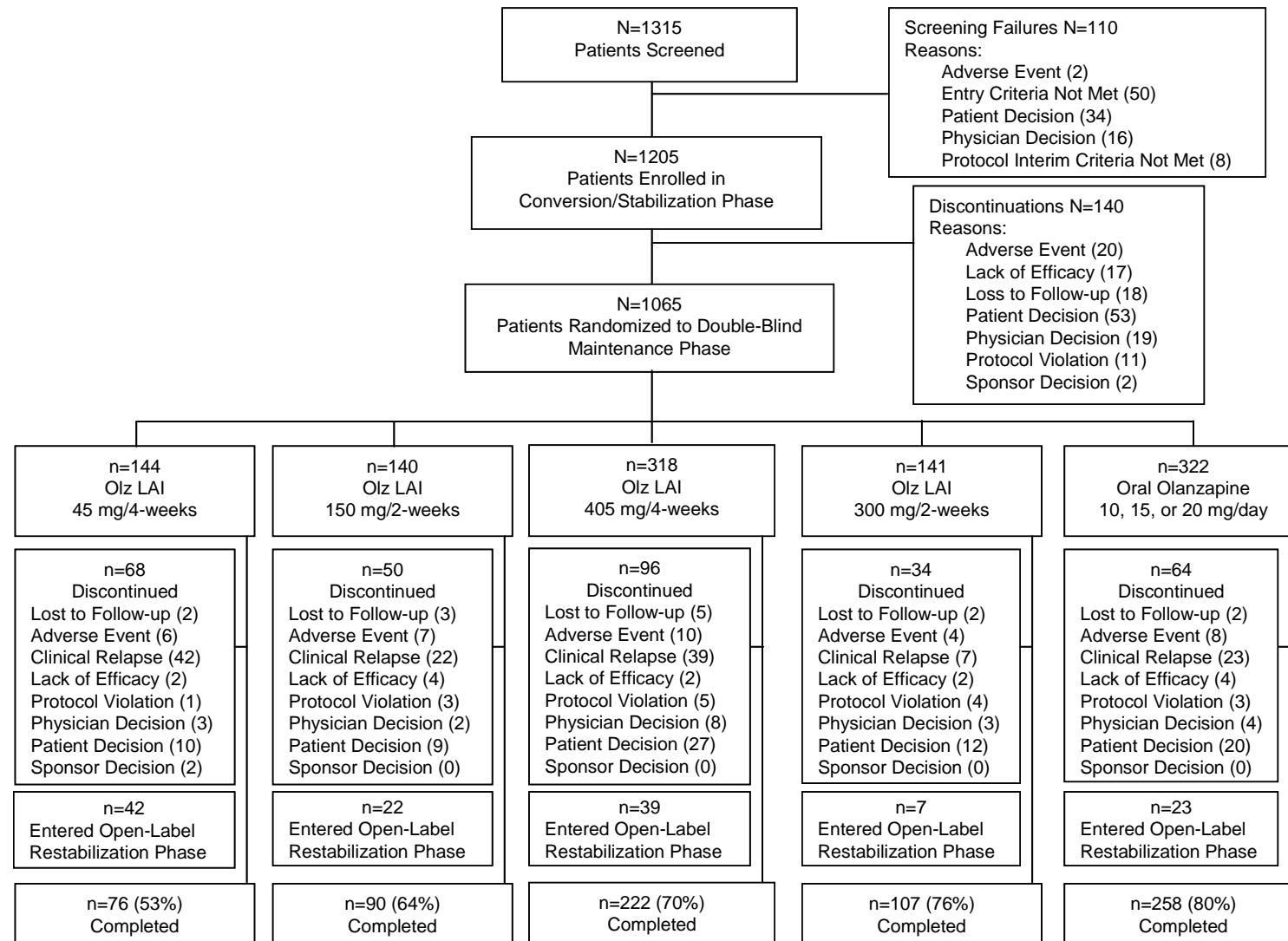
Olz LAI = olanzapine long-acting injection; oral olz = oral olanzapine; ref = reference; med = medium. Within-group difference calculated by one sample t-test; pairwise treatment comparisons calculated using analysis of variance.

^a p<0.05 vs. Olz LAI 150 mg/2-weeks

^b p<0.05 vs. Olz LAI 405 mg/4-weeks

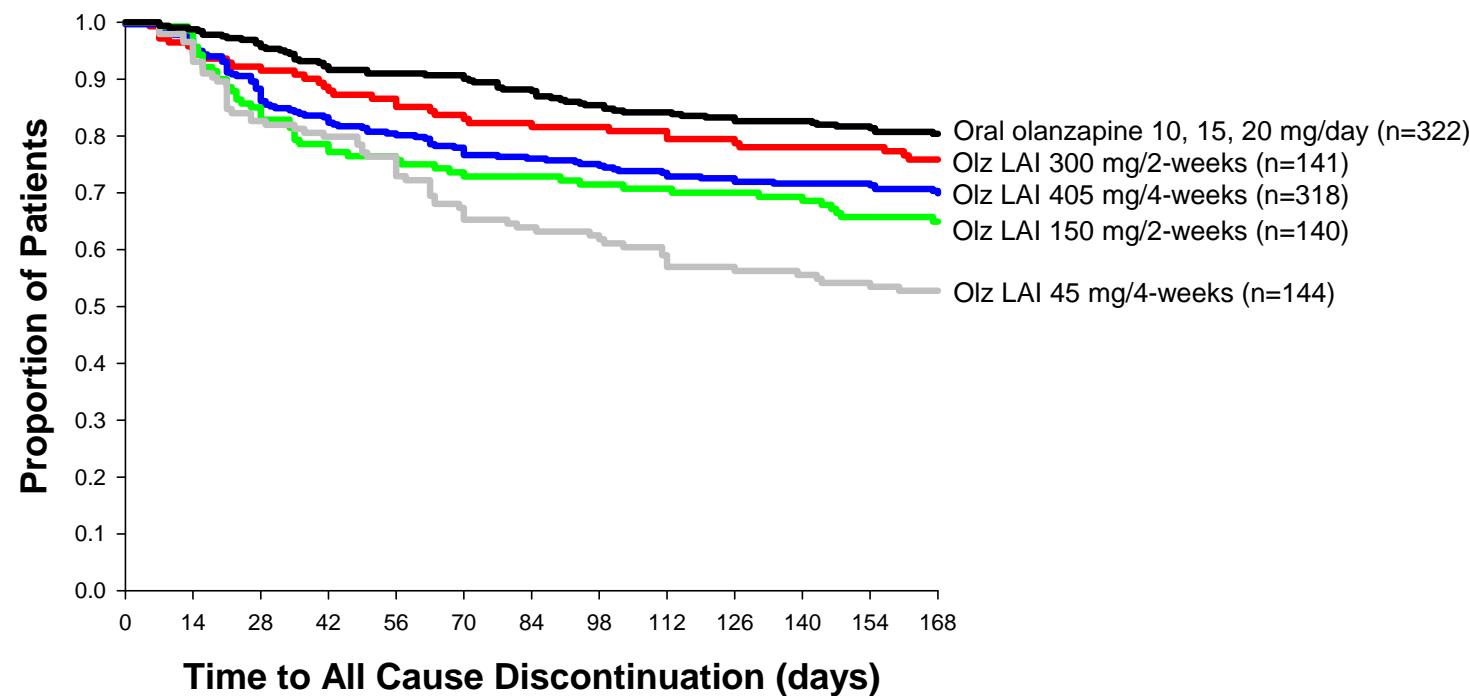
^c p<0.05 vs. oral olanzapine

Figure 1 (Supplemental section). Summary of Disposition of Patients With Schizophrenia in a 24-Week, Randomized, Double-Blind Trial of Olanzapine Long-Acting Injection and Oral Olanzapine



Olz LAI = olanzapine long-acting injection.

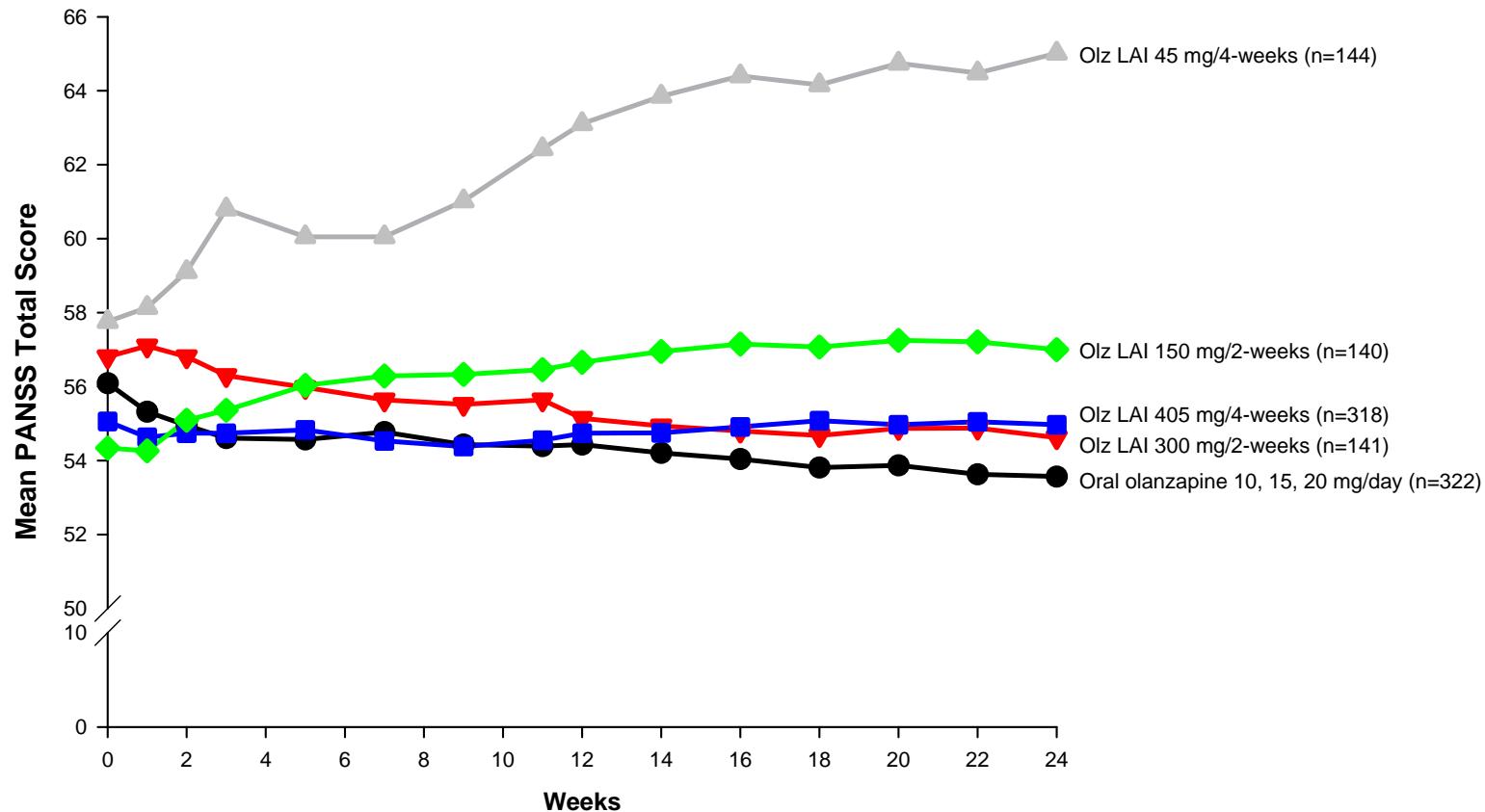
Figure 2 (Supplemental section). Kaplan-Meier Estimates of Time to All Cause Discontinuation Among Patients With Schizophrenia Treated with Olanzapine Long-Acting Injection and Oral Olanzapine During a 24-Week Double-Blind Maintenance Phase



Olz LAI = olanzapine long-acting injection.

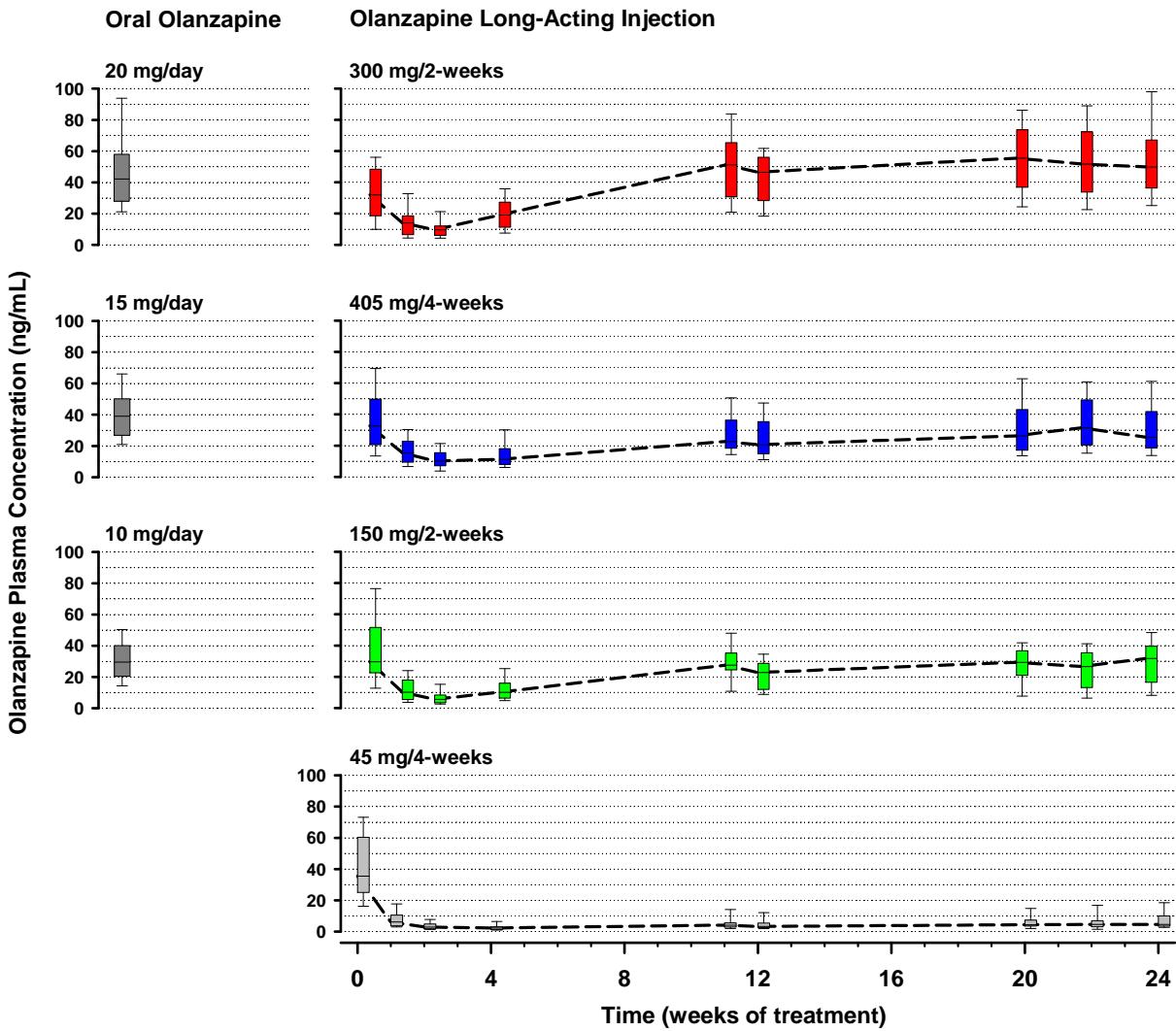
Log-rank test for Olz LAI 300 mg/2-weeks, 405 mg/4-weeks, and oral olanzapine vs. Olz LAI 45 mg/4-weeks and for oral olanzapine vs. Olz LAI 150 mg/2-weeks, all $p < 0.001$. Oral olanzapine vs. Olz LAI 405 mg/4-weeks, $p = 0.001$. Olz LAI 150 mg/2 weeks vs. 45 mg/4-weeks, $p = 0.065$.

Figure 3 (Supplemental section). Visitwise (LOCF) Mean PANSS Total Score for Patients with Schizophrenia Treated with Olanzapine Long-Acting Injection or Oral Olanzapine for 24 Weeks



Olz LAI = olanzapine long-acting injection.

Figure 4 (Supplemental section). Olanzapine Plasma Concentrations Over Time for the Olanzapine Long-Acting Injection Groups Relative to the Olanzapine Concentrations at Any Time for Patients Treated with 10, 15, or 20 mg/day Oral Olanzapine



For box-and-whiskers plots, bottom and top borders of box are the 25th and 75th percentiles, respectively; bottom and top whiskers are the 10th and 90th percentiles, respectively. Dashed lines connect median (50th percentile) concentrations. These graphs illustrate summary detail of analyzable olanzapine concentration measurements (2419 blood samples collected from 341 patients) taken at infrequent intervals over a period of 24 weeks. Olz LAI = olanzapine long-acting injection.