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Supplementary Material

Article Title: Safety and Tolerability of Starting Aripiprazole Lauroxil With Aripiprazole Lauroxil NanoCrystal Dispersion in 1 Day Followed by Aripiprazole Lauroxil Every 2 Months Using Paliperidone Palmitate Monthly as an Active Control in Patients With Schizophrenia: A Post Hoc Analysis of a Randomized Controlled Trial

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LIST OF SUPPLEMENTARY MATERIAL FOR THE ARTICLE

DISCLAIMER

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Supplementary Table 1. Schedule of Assessments[a]

Procedure	Required Inpatient Stay								Outpatient Visits							
	Visit 1 Screening	Visit 2 Baseline	Visit 3						Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11/ EOT/EOS/ET
	Days −7 to −1	Day 1	Days 2–3	Day 4	Days 5–7	Day 8	Days 9–14	Day 15	Day 22	Day 29	Day 36	Day 64	Day 92	Day 120	Day 148	Day 176
									±1 day	±3-day window, anchored to the prior injection						
Physical examination	X							X								X
Weight	X	X						X		X		X		X		X
Biochemistry, hematology, urinalysis (including prolactin)	X	X				X		X			X	X	X	X	X	X
Vital signs	X	X				X		X			X	X	X	X	X	X
12-lead ECG	X	X				X		X			X	X	X	X	X	X
Injection site evaluation		X	X			X	X	X			X	X	X	X	X	
AIMS		X								X						X
BARS/SAS	X	X		X		X		X		X		X				X
C-SSRS	X	X				X		X	X	X	X	X	X	X	X	X
ESS								X	X	X		X	X			X
AE monitoring	X															

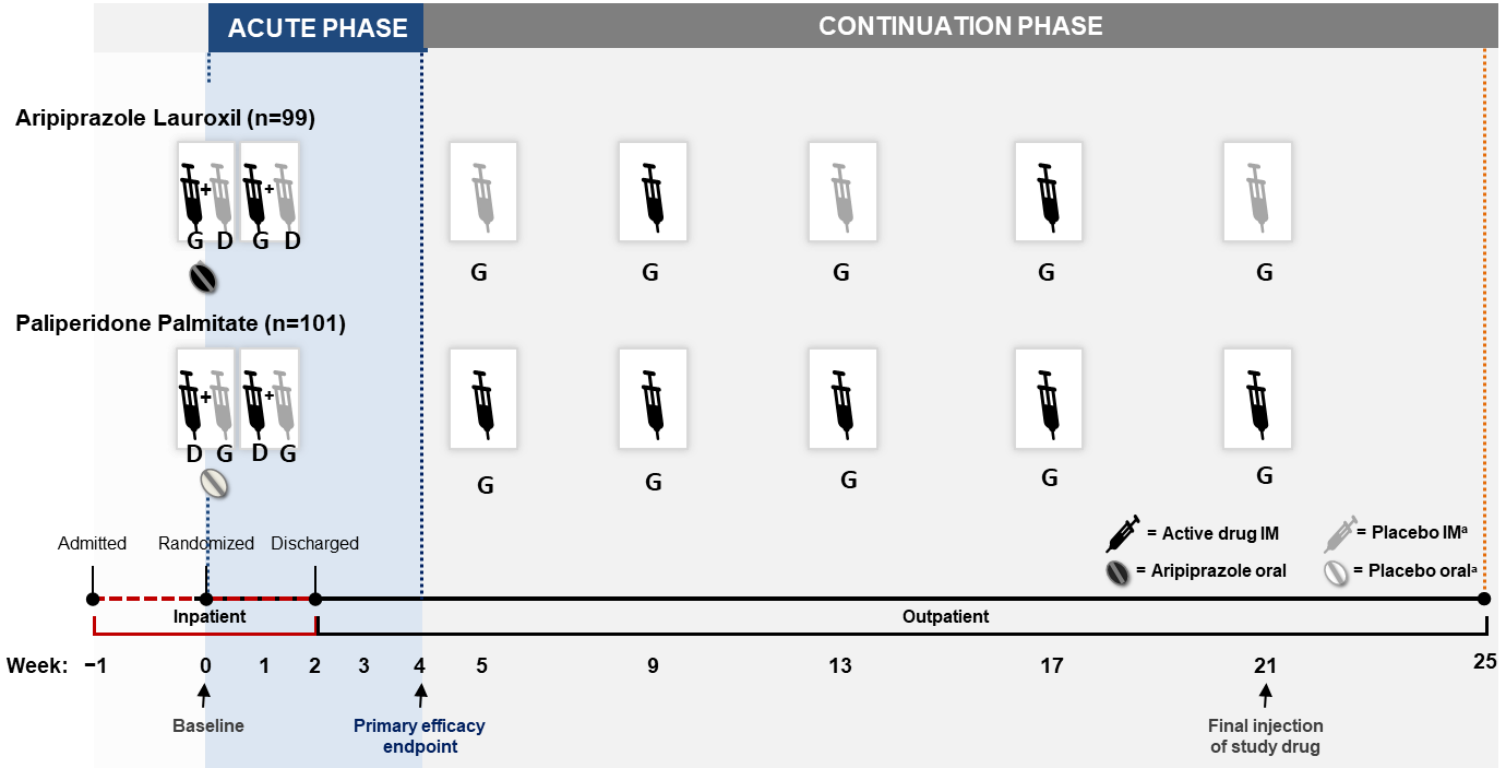
[a]Not all assessment parameters are shown; the parameters indicated in the table are limited to those described in this analysis.
Abbreviations: AE, adverse event; AIMS, Abnormal Involuntary Movement Scale; BARS, Barnes Akathisia Rating Scale; C-SSRS, Columbia-Suicide Severity Rating Scale; ECG, electrocardiogram; EOS, end of study; EOT, end of treatment; ESS, Epworth Sleepiness Scale; ET, early termination; SAS, Simpson-Angus Scale.

Supplementary Table 2. Patient Demographics and Baseline Characteristics (Safety Population)

	Aripiprazole Lauroxil (n=99)	Paliperidone Palmitate (n=101)	Total (N=200)
Age, mean (SD), years	43.5 (9.7)	43.4 (10.8)	43.4 (10.3)
Male, n (%)	73 (73.7)	76 (75.2)	149 (74.5)
BMI, mean (SD), kg/m^2	28.2 (5.5)	27.9 (5.1)	28.0 (5.3)
Prior antipsychotic exposure, n (%)			
Aripiprazole	5 (5.1)	7 (6.9)	12 (6.0)
Risperidone/paliperidone	31 (31.3)	31 (30.7)	62 (31.0)
Both aripiprazole and risperidone/paliperidone	51 (51.5)	49 (48.5)	100 (50.0)
Neither aripiprazole nor risperidone/paliperidone	12 (12.1)	14 (13.9)	26 (13.0)
PANSS total score, mean (SD)[a]	94.1 (9.0)	94.6 (8.4)	94.4 (8.7)

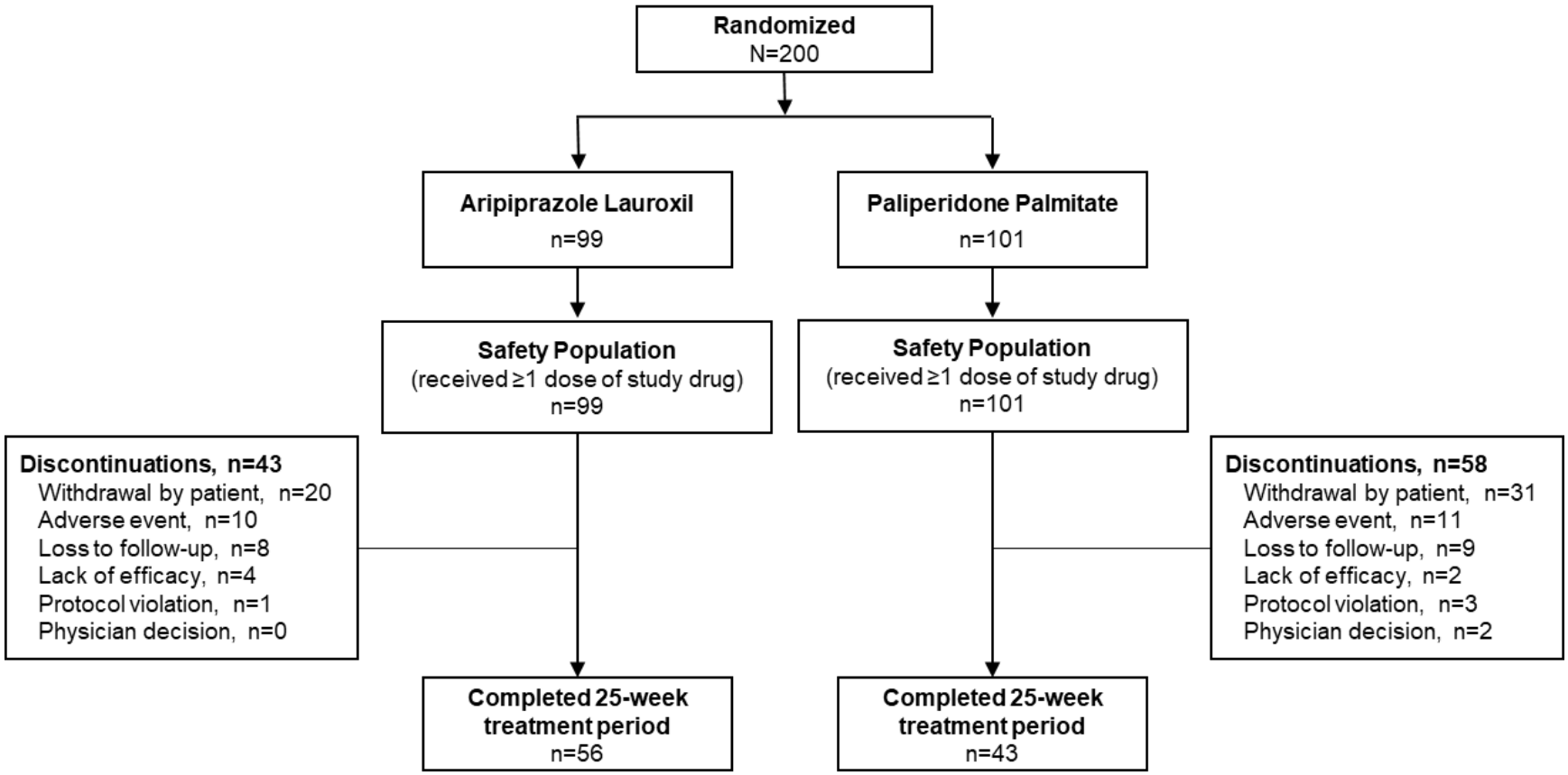
[a]Based on patients with ≥1 postbaseline PANSS assessment (aripiprazole lauroxil, n=96; paliperidone palmitate, n=99). Baseline was defined as the last nonmissing assessment before the first dose of study drug on day 1.
Abbreviations: BMI, body mass index; PANSS, Positive and Negative Syndrome Scale; SD, standard deviation.

Supplementary Figure 1. Study Injection Schedule

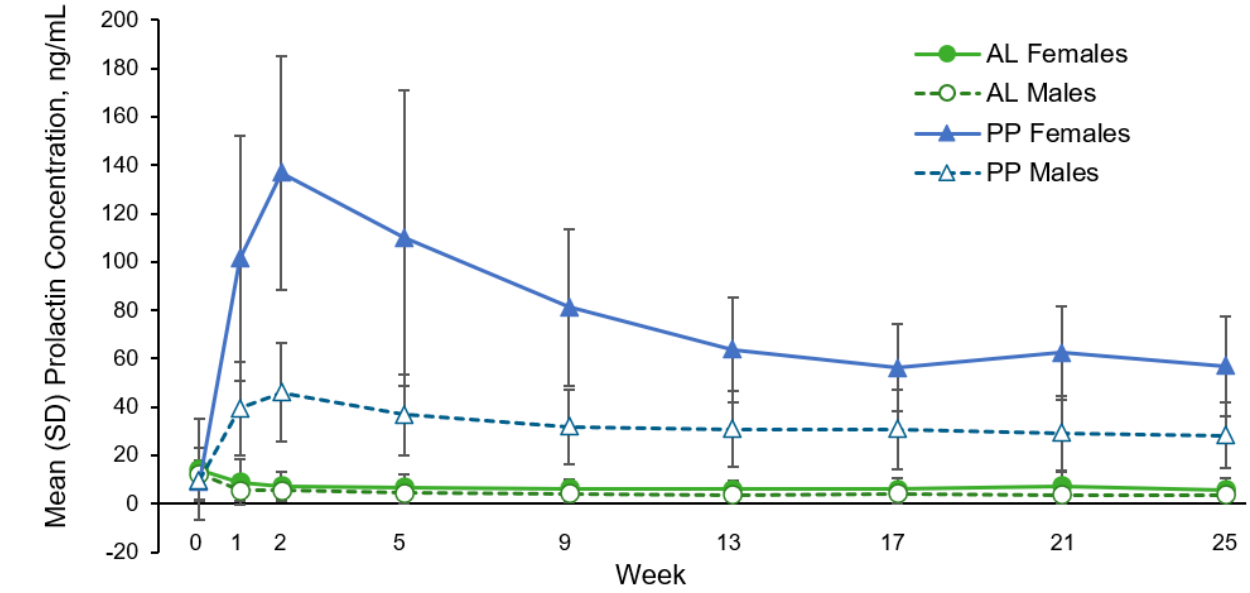


[a]Because AL initiation required gluteal injection and PP initiation required deltoid injection, both groups were administered placebo injections during initiation (days 1 and 8) to maintain blinding; the AL group also received placebo injections at weeks 5, 13, and 21 to match the PP dosing schedule. The PP group received an oral placebo tablet on day 1 to match the oral dose of aripiprazole in the AL initiation regimen.
Abbreviations: AL, aripiprazole lauroxil; D, deltoid; G, gluteal; IM, intramuscular; PP, paliperidone palmitate.

Supplementary Figure 2. Study Patient Flow



Supplementary Figure 3. Prolactin Concentrations Over Time by Sex



AL Females, n:	26	21	20	20	19	18	18	18	18
AL Males, n:	73	66	63	54	46	41	39	38	38
PP Females, n:	25	24	20	12	8	7	7	7	7
PP Males, n:	76	72	68	55	47	41	39	38	36

Abbreviations: AL, aripiprazole lauroxil; PP, paliperidone palmitate; SD, standard deviation.