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Supplementary Material

Article Title: Efficacy and Safety of a 2-Month Formulation of Aripiprazole Lauroxil With 1-Day Initiation in Patients Hospitalized for Acute Schizophrenia Transitioned to Outpatient Care: Phase 3, Randomized, Double-Blind, Active Control ALPINE Study

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List of Supplementary Material for the article

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Supplementary Table 1. Patient Disposition Up to Week 4

	Aripiprazole Lauroxil (n=99)	Paliperidone Palmitate (n=101)	Total (N=200)
Completed first 4 weeks of treatment, n (%)	79 (79.8)	75 (74.3)	154 (77.0)
Discontinued during first 4 weeks, n (%)	20 (20.2)	25 (24.8)	45 (22.5)
Reasons for discontinuation, n (%)			
Withdrawal by patient	10 (10.1)	16 (15.8)	26 (13.0)
Adverse event	4 (4.0)	5 (5.0)	9 (4.5)
Lost to follow-up	3 (3.0)	3 (3.0)	6 (3.0)
Lack of efficacy	2 (2.0)	1 (1.0)	3 (1.5)
Protocol violation	1 (1.0)	0	1 (0.5)

Supplementary Table 2. Demographics and Baseline Characteristics[a]

	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)
Men, n (%)	73 (73.7)	76 (75.2)	149 (74.5)
Race, n (%)			
Black or African American	72 (72.7)	78 (77.2)	150 (75.0)
White	25 (25.3)	17 (16.8)	42 (21.0)
Asian	2 (2.0)	4 (4.0)	6 (3.0)
Multiple races[b]	0	2 (2.0)	2 (1.0)
Ethnicity, n (%)			
Hispanic or Latino	8 (8.1)	11 (10.9)	19 (9.5)
Weight, mean (SD), kg	84.8 (19.8)	85.0 (18.8)	84.9 (19.2)
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[c]	31 (31.3)	31 (30.7)	62 (31.0)
Both aripiprazole and risperidone[c]	51 (51.5)	49 (48.5)	100 (50.0)
Neither aripiprazole nor risperidone[c]	12 (12.1)	14 (13.9)	26 (13.0)
$PANSS_T$, mean (SD)[d]	94.1 (9.0)	94.6 (8.4)	94.4 (8.7)

[a]Safety population (patients who received ≥1 dose of study drug).
[b]A patient who reported ≥1 race is counted once under this category.
[c]"Risperidone" includes risperidone or paliperidone (oral or LAI).
[d]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; LAI, long-acting injectable; $PANSS_T$, Positive and Negative Syndrome Scale total score.

Supplementary Table 3. Last Known Antipsychotic Prior to Study Entry

Patients, n (%)	Aripiprazole Lauroxil (n=99)	Paliperidone Palmitate (n=101)	Total (N=200)
Patients with antipsychotic exposure in the 30 days before screening	69 (69.7)	69 (68.3)	138 (69.0)
Quetiapine	17 (17.2)	20 (19.8)	37 (18.5)[a]
Olanzapine	21 (21.2)	13 (12.9)	34 (17.0)
Risperidone/paliperidone	16 (16.2)	14 (13.9)	30 (15.0)[b]
Aripiprazole	8 (8.1)	13 (12.9)	21 (10.5)
Other atypical antipsychotic	4 (4.0)	4 (4.0)	8 (4.0)[c]
Other conventional antipsychotic	3 (3.0)	5 (5.0)	8 (4.0)[d]
Patients without antipsychotic exposure in the 30 days before screening	30 (30.3)	32 (31.7)	62 (31.0)

[a]Includes quetiapine (n=4) and quetiapine fumerate (n=33).
[b]Includes risperidone (n=25) and paliperidone (n=5).
[c]Asenapine (n=1), brexpiprazole (n=1), iloperidone (n=1), lurasidone (n=2), and ziprasidone (n=3).
[d]Fluphenazine (n=3), haloperidol (n=4), and thiothixene (n=1).

Supplementary Table 4. Serious Adverse Events with Aripiprazole Lauroxil

	Aripiprazole Lauroxil (n=99)	
Patients, n (%)	**Week 0 to Week 4**	**Cumulative AEs, Week 0 to Week 25[a]**
Serious AEs	2 (2.0)	8 (8.1)
Schizophrenia	1 (1.0)	5 (5.1)
Psychotic disorder	0	2 (2.0)
Generalized tonic-clonic seizure	1 (1.0)	1 (1.0)
Leukocytosis	0	1 (1.0)
Hypercalcemia	0	1 (1.0)
Renal failure	0	1 (1.0)
Suicidal ideation	0	1 (1.0)
Suicide attempt	0	1 (1.0)

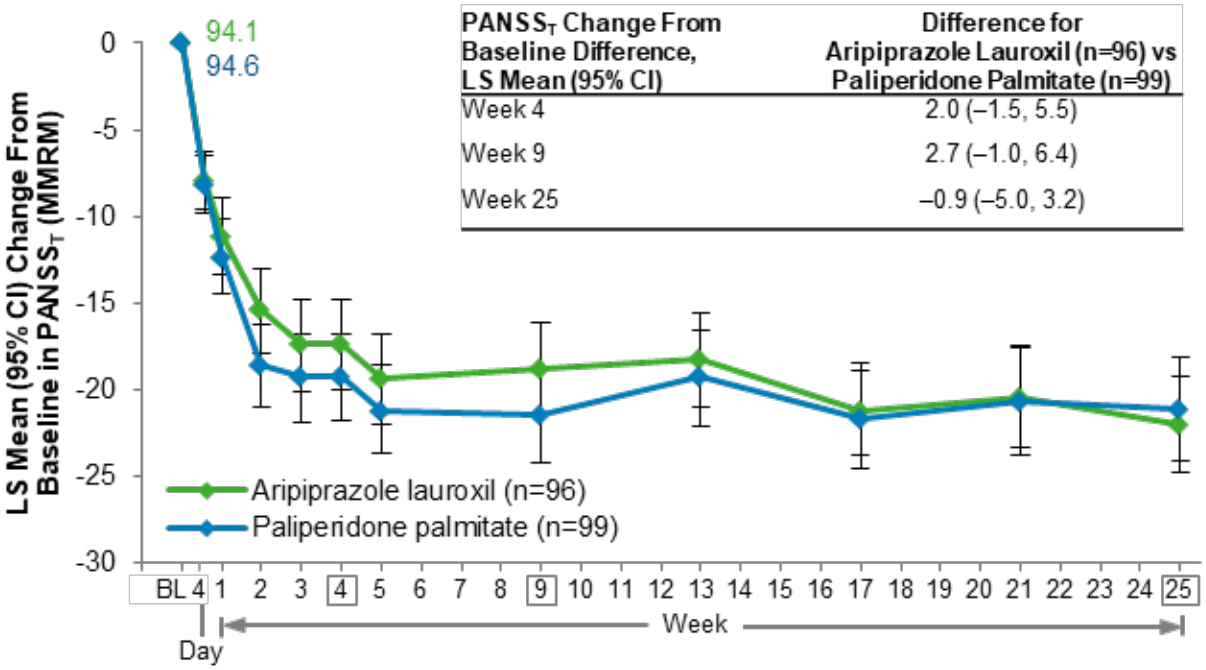
[a]AEs listed in the “week 0 to week 4” column are also included in this column.
Abbreviation: AE, adverse event.

Supplementary Table 5. Serious Adverse Events with Paliperidone Palmitate

	Paliperidone Palmitate (n=101)	
Patients, n (%)	**Week 0 to Week 4**	**Cumulative AEs, Week 0 to Week 25[a]**
Serious AEs	3 (3.0)	7 (6.9)
Schizophrenia	2 (2.0)	2 (2.0)
Alcohol poisoning	1 (1.0)	1 (1.0)
Psychotic symptom	1 (1.0)	1 (1.0)
Suicide attempt	0	1 (1.0)
Overdose	0	1 (1.0)
Road traffic accident	0	1 (1.0)[b]
Bone deformity	0	1 (1.0)
Dystonia	0	1 (1.0)
Depression	0	1 (1.0)

[a]AEs listed in the "week 0 to week 4" column are also included in this column.
[b]1 serious AE leading to death (road traffic accident) occurred in the paliperidone palmitate group; the event was assessed by the investigator as definitely not related to treatment.
Abbreviation: AEs, adverse events.

Supplementary Figure 1. PANSS Total Score Between-Group Analysis Using MMRM.[a]



[a]LS mean (95% CI) PANSS$_T$ changes from baseline using MMRM (secondary endpoint). Error bars represent 95% CIs. Mean baseline PANSS$_T$ is indicated at the first time point (aripiprazole lauroxil, green; paliperidone palmitate, blue). Gray boxes indicate secondary endpoints.
Abbreviations: BL, baseline; LS, least squares; MMRM, mixed-model repeated measures; PANSS$_T$, Positive and Negative Syndrome Scale total score.