THE JOURNAL OF
CLINICAL PSYCHIATRY
THE OFFICIAL JOURNAL OF THE AMERICAN SOCIETY OF CLINICAL PSYCHOPHARMACOLOGY

Supplementary Material

Article Title: Beyond 52-Week Long-Term Safety: Long-Term Outcomes of Aripiprazole Lauroxil for Patients With Schizophrenia Continuing in an Extension Study

Author(s): John Lauriello, MD; Amy Claxton, PhD; Yangchun Du, PhD; and Peter J. Weiden, MD

DOI Number: https://doi.org/10.4088/JCP.19m12835

List of Supplementary Material for the article

1. Table 1 — Disposition of Patients and Summary of Adverse Events in the Combined 52-Week and Long-term Studies (Safety Population)
2. Figure 1 — PANSS General Psychopathology Score From Week 12 Through Week 124 (MMRM Analysis)

Disclaimer

This Supplementary Material has been provided by the author(s) as an enhancement to the published article. It has been approved by peer review; however, it has undergone neither editing nor formatting by in-house editorial staff. The material is presented in the manner supplied by the author.

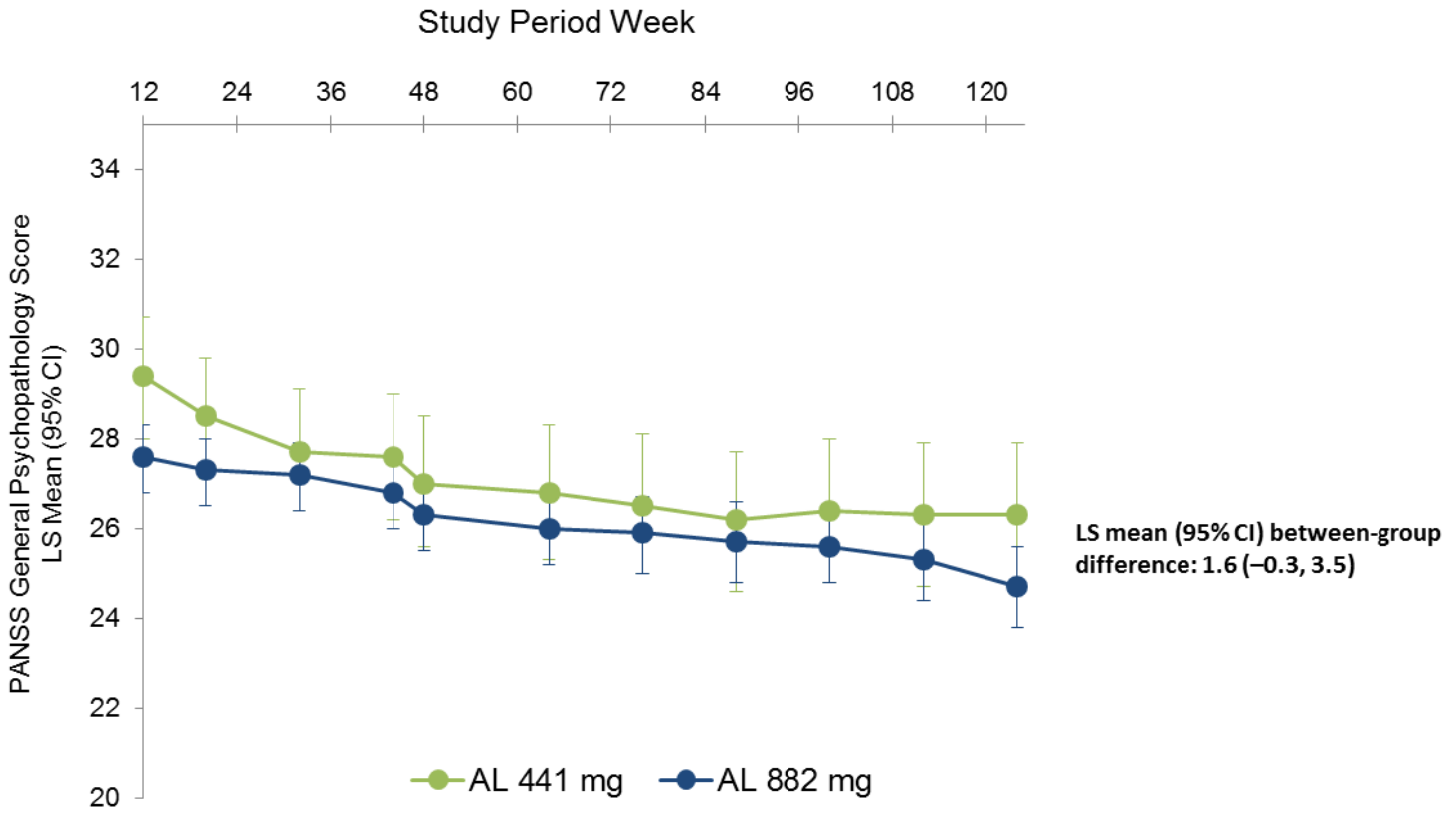
Supplementary Table 1. Disposition of Patients and Summary of Adverse Events in the Combined 52-Week and Long-term Studies (Safety Population)

Patients, n (%)	AL 441 mg every 4 weeks n = 110	AL 882 mg every 4 weeks n = 368	Total N = 478
Completed 52-week safety study[a]	75 (68.2)	251 (68.2)	326 (68.2)
Entered LTE study	65	226	291
Completed LTE study	61 (93.8)[b]	198 (87.6)[b]	259 (89.0)[b]
Reasons for early discontinuation in the combined 52-week and LTE studies			
Withdrawal by patient	23 (20.9)	60 (16.3)	83 (17.4)
Lost to follow-up	3 (2.7)	32 (8.7)	35 (7.3)
Adverse event	3 (2.7)	31 (8.4)	34 (7.1)
Lack of efficacy	6 (5.5)	7 (1.9)	13 (2.7)
Other (unspecified)	2 (1.8)	8 (2.2)	10 (2.1)
Physician decision	1 (0.9)	4 (1.1)	5 (1.0)
Protocol violation	1 (0.9)	1 (0.3)	2 (0.4)
Noncompliance with study drug	0	1 (0.3)	1 (0.2)
Pregnancy	0	1 (0.3)	1 (0.2)
Any AE	58 (52.7)	217 (59.0)	275 (57.5)
Drug-related AE	35 (31.8)	130 (35.3)	165 (34.5)
Any SAE	0	18 (4.9)	18 (3.8)
SAEs leading to death	0	2 (0.5)	2 (0.4)
AEs occurring in ≥2% of patients overall			
Insomnia	8 (7.3)	53 (14.4)	61 (12.8)
Headache	12 (10.9)	20 (5.4)	32 (6.7)

Patients, n (%)	AL 441 mg every 4 weeks n = 110	AL 882 mg every 4 weeks n = 368	Total N = 478
Weight increased	10 (9.1)	19 (5.2)	29 (6.1)
Anxiety	4 (3.6)	23 (6.3)	27 (5.6)
Nasopharyngitis	8 (7.3)	17 (4.6)	25 (5.2)
Akathisia	5 (4.5)	18 (4.9)	23 (4.8)
Schizophrenia	6 (5.5)	17 (4.6)	23 (4.8)
Tremor	3 (2.7)	18 (4.9)	21 (4.4)
Injection site pain	1 (0.9)	18 (4.9)	19 (4.0)
Diarrhea	6 (5.5)	11 (3.0)	17 (3.6)
Weight decreased	3 (2.7)	14 (3.8)	17 (3.6)
Nausea	4 (3.6)	11 (3.0)	15 (3.1)
Hypertension	3 (2.7)	12 (3.3)	15 (3.1)
Dizziness	4 (3.6)	9 (2.4)	13 (2.7)
Toothache	5 (4.5)	8 (2.2)	13 (2.7)
URTI	1 (0.9)	12 (3.3)	13 (2.7)
Agitation	2 (1.8)	10 (2.7)	12 (2.5)
Arthralgia	4 (3.6)	8 (2.2)	12 (2.5)
Asthenia	3 (2.7)	9 (2.4)	12 (2.5)
Cough	3 (2.7)	9 (2.4)	12 (2.5)
Influenza	3 (2.7)	8 (2.2)	11 (2.3)
Back pain	2 (1.8)	8 (2.2)	10 (2.1)

[a]These patients were censored for Kaplan-Meier analysis.
[b]Percentage is based on the number of patients who entered the long-term extension study.
AE, adverse event; SAE, serious adverse event; LTE, long-term extension; URTI, upper respiratory tract infection.

Supplementary Figure 1. PANSS General Psychopathology Score From Week 12 Through Week 124 (MMRM Analysis)



AL, aripiprazole lauroxil; CI, confidence interval; LS, least squares; MMRM, mixed-effects model for repeated measures; PANSS, Positive and Negative Syndrome Scale.