**Pharmacokinetic Evaluation of a One-Day Treatment Initiation Option for Starting Long-Acting Aripiprazole Lauroxil for Schizophrenia**

# **Supplemental Digital Content 6**

## SUPPLEMENTAL TABLE S2. Adverse Events in ≥2% of Patients Overall

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Patients, n (%)** | **1-Day Initiation AL 441 mg**\* | **1-Day Initiation AL 882 mg**† | **21-Day Initiation AL 441 mg**‡ | **21-Day Initiation AL 882 mg**§ |
| N | 39 | 41 | 40 | 41 |
| Any AE | 26 (66.7) | 28 (68.3) | 24 (60.0) | 28 (68.3) |
| Gastrointestinal disordersDyspepsiaDiarrheaToothacheNauseaVomiting  | 9 (23.1)3 (7.7)1 (2.6)1 (2.6)2 (5.1)0 | 4 (9.8)2 (4.9)2 (4.9)002 (4.9) | 6 (15.0)1 (2.5)1 (2.5)3 (7.5)01 (2.5) | 8 (19.5)3 (7.3)1 (2.4)1 (2.4)2 (4.9)1 (2.4) |
| General disorders and administration-site conditions‖Injection-site painInjection-site indurationFatigueInjection-site swelling | 10 (25.6)9 (23.1)2 (5.1)00 | 9 (22.0)8 (19.5)2 (4.9)1 (2.4)0 | 14 (35.0)11 (27.5)2 (5.0)2 (5.0)2 (5.0) | 10 (24.4)9 (22.0)1 (2.4)1 (2.4)1 (2.4) |
| Immune system disorders | 0 | 3 (7.3) | 1 (2.5) | 0 |
| Infections and infestationsURTINasopharyngitis | 3 (7.7)01 (2.6) | 7 (17.1)2 (4.9)2 (4.9) | 5 (12.5)2 (5.0)0 | 5 (12.2)3 (7.3)2 (4.9) |
| Injury, poisoning, and procedural complicationsFall  | 2 (5.1)1 (2.6) | 2 (4.9)1 (2.4) | 4 (10.0)1 (2.5) | 3 (7.3)1 (2.4) |
| InvestigationsWeight increasedWeight decreased | 6 (15.4)5 (12.8)1 (2.6) | 7 (17.1)4 (9.8)2 (4.9) | 4 (10.0)2 (5.0)0 | 5 (12.2)1 (2.4)2 (4.9) |
| Musculoskeletal and connective tissue disorders | 4 (10.3) | 3 (7.3) | 3 (7.5) | 1 (2.4) |
| Nervous system disordersHeadacheAkathisia | 8 (20.5)3 (7.7)1 (2.6) | 9 (22.0)3 (7.3)3 (7.3) | 6 (15.0)5 (12.5)0 | 7 (17.1)5 (12.2)2 (4.9) |
| Psychiatric disordersInsomniaAnxiety | 6 (15.4)2 (5.1)2 (5.1) | 5 (12.2)2 (4.9)4 (9.8) | 4 (10.0)3 (7.5)2 (5.0) | 5 (12.2)3 (7.3)0 |
| Respiratory, thoracic, and mediastinal disorders | 2 (5.1) | 2 (4.9) | 1 (2.5) | 1 (2.4) |
| Vascular disordersHypertension  | 00 | 1 (2.4)1 (2.4) | 00 | 3 (7.3)3 (7.3) |

AE, adverse event; AL, aripiprazole lauroxil; ALNCD, aripiprazole lauroxil NanoCrystal dispersion; ISR, injection-site reaction; URTI, upper respiratory tract infection.

\*30 mg oral aripiprazole plus ALNCD (gluteal) plus AL 441 mg (deltoid) on Day 1 followed by oral placebo for 20 days.

†30 mg oral aripiprazole plus ALNCD (gluteal) plus AL 882 mg (contralateral gluteal) on Day 1 followed by oral placebo for 20 days.

‡15 mg oral aripiprazole plus placebo injection (gluteal) plus AL 441 mg (deltoid) on Day 1 followed by 20 days of 15 mg oral aripiprazole.

§15 mg oral aripiprazole plus placebo injection (gluteal) plus AL 882 mg (contralateral gluteal) on Day 1 followed by 20 days of 15 mg oral aripiprazole.

‖A breakdown of ISRs by injected product is included in Table 2.