

groups from baseline to end of follow-up, analyzed using MMRM.

**RESULTS:** Overall, 432/478 patients entering the initial 52-week study were included in the post hoc analysis. For the AL 441 and 882 mg groups, respectively, baseline scores (mean ± SD) were 59.91 ± 16.25 and 56.27 ± 12.89 (PANSS), and 2.99 ± 0.97 and 2.79 ± 0.79 (CGI-S scale). Approximately 49% of patients (211/432) remained for the entire 112-week follow-up. Over this period, the trajectory of PANSS scores improved significantly compared with baseline for both the 441 and 882 mg groups, with changes from baseline (least squares mean ± SE) of -5.46 ± 0.92 (P < .0001) and -4.99 ± 0.53 (P < .0001), respectively. CGI-S scale scores had similar improvement: changes from baseline of -0.32 ± 0.07 (P < .0001) and -0.28 ± 0.04 (P < .0001) for the AL 441 and 882 mg groups, respectively. Overall, AL was well tolerated, with a safety profile over a 2-year follow-up that was consistent with the initial 52-week safety results.

**CONCLUSION:** This post hoc analysis demonstrates the safety and continued therapeutic efficacy of long-term treatment with AL in patients with schizophrenia. There were no apparent dose differences in the trajectory of symptom changes over the course of a 2-year follow-up. Funding Acknowledgements: This study was funded by Alkermes, Inc.

## 64 Aripiprazole Long-acting Injectable in Schizophrenia. An 18-month Follow-up and Mirror-image Study

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**ABSTRACT:** Study Objectives:

1. To assess the effectiveness, functionality and tolerability of Aripiprazole long-acting injectable (ALAI) in patients with stable schizophrenia
2. Compare hospitalizations and emergency assists during 18-month period before (retrospective period) and after (prospective period) switch to ALAI

**METHOD:** The study sample involved 18 patients with stable schizophrenia (DSM 5 criteria) who started treatment with ALAI between January-December 2016. Variables: age, gender, psychopharmacological treatment.

TABLE 1. Efficacy, functionality and treatment compliance results

|                      | Baseline      | 6 Months       | 12 Months      | 18 Months      |
|----------------------|---------------|----------------|----------------|----------------|
| BPRS                 | 20.53 (±3.17) | 17.81 (±3.16)  | 17.46 (±3.11)  | 17.03 (±3.13)  |
| BPRS-P               | 6.94 (±1.03)  | 6.14 (±1.05)   | 6.09 (±1.03)   | 6.16 (±1.07)   |
| BPRS-N               | 7.96 (±0.73)  | 6.44 (±0.69)** | 6.11 (±0.73)** | 6.01 (±0.63)** |
| I.C.G. S.I           | 4.24 (±0.83)  | 3.10 (±0.84)** | 3.08 (±0.81)** | 3.09 (±0.81)** |
| PSP                  | 55.95 (±4.05) | 63.08 (±5.77)  | 63.89 (±5.05)  | 66.33 (±5.37)* |
| Treatment compliance | 100%          | 66.6%          | 66.6%          | 61.1%          |

\*p < 0.05, \*\*p < 0.01

- Follow-up study: Prospective assessments were performed at baseline and at 3, 6, 9, 12, 15 and 18 months:

- Brief Psychiatric rating Scale (BPRS)
- Global Clinical Impression Scale (ICG-SI)
- Personal and social Performance (PSP)
- Side effects reported

- Mirror-image study: 18-month before and after switch

- Number of hospitalizations and emergency assists

The study was performed in accordance with the Declaration of Helsinki and all the participants provided written consent for participation.

Student's t-test and Chi-square test were used to assess differences between baseline evaluation and subsequent visits. For mirror-image analysis test Z and MacNemar was used.

### RESULTS:

a) Efficacy and functionality: At the end of the study we observed:

- A statistically significant: reduction in the total score of ICG-SI, and increase in the total score of PSP
- A reduction in the total score of BPRS.

There is an indirect correlation between age and changes in the score on: BPRS and ICG-SI (p < 0.05) and PSP scale (p < 0.05)

b) Tolerability: The most frequent side effect with an incidence of 22% was transient mild insomnia

c) Psychopharmacological treatment: The percentage of patients on monotherapy increased from 39.6% baseline to 66.6%, and treatment with Biperidene decreased from 27.5% to 5.5% at the end of the study

d) Number of hospitalizations and emergency assist:

- 12 hospital admission during 18-month period before switch to ALI, and 3 hospital admission 18-month after switch
- 24 emergency assist during 18-month period before switch to ALI, and 7 emergency assist 18-month after switch

e) Treatment compliance: shown in Table 1.

**CONCLUSIONS:** ALAI can be effective therapy for the treatment of patients with schizophrenia: improves psychopathological symptoms, functionality and can

prevent hospitalizations and emergency visits. In addition, ALAI is well tolerated, achieving a high percentage of patients in monotherapy.

## 65

### A Retrospective Study of Aripiprazole Long-acting Once-Monthly Introduction Patterns in Galicia

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**ABSTRACT:** Background: Antipsychotic drug treatment is a key component of multiple psychiatric treatment algorithms. Second-generation long-acting injectable antipsychotics (LAIs) have been shown to improve adherence in numerous clinical trials. Patients who can benefit from LAIs therapy can be treated with aripiprazole long acting once-monthly (AOM). However the nature of the introduction patterns of AOM is not well characterized in clinical practice.

**METHODS:** A retrospective observational study of AOM introduction was conducted on 157 patients aged 18–75 years-old (95 males, 62 females) who were initiated on AOM treatment between January 2017 – December 2017 in two independent Mental Health Units in the autonomous region of Galicia (Spain). An analysis of the different trends in switching strategies and its adaptation to the prescribing information was carried out. Results were compared between different dose treatment plans and a comparison between inpatients and outpatients' outcomes was also undertaken. Additional data regarding off-label use was obtained from the sample.

**RESULTS:** The sample was composed of 157 patients: 31% diagnosed of Schizophrenia (n = 48), 14% Schizoaffective Disorder (n = 22), 21% Delusional Disorder (n = 33), 17% Bipolar Disorder (n = 27), 10% Brief Psychotic Disorder (n = 15), 4% Psychotic Disorder Not Specified (n = 6), 2% Obsessive-Compulsive Disorder (n = 3), 2% Paranoid Personality Disorder (n = 3). Regarding the location of the first dose administration: 44% (n = 69) were administered in an Acute Psychiatric Inpatient Unit, 44% (n = 65) were administered in Mental Health Outpatient Clinics, 11% (n = 18) in Psychiatric Day

Hospitals and 3% (n = 5), in Assertive Community Treatment Programs. 74% (n = 116) of patients received an initial dose of 400mg of AOM whereas 26% (n = 41) were given 300mg of AOM. The previous antipsychotic was aripiprazole orale (OA) in 61% (n = 96) of the cases. The most frequent switch between LAIs was “immediate switch” and in the switch between orale antipsychotics and AOM “tapering and overlap” was found to be the most common pattern. The average dose was 20 mg/day in all groups except for patients diagnosed with Delusional Disorder (15 mg/day). The average duration of treatment with OA after the first dose was: 32 days for patients with Schizophrenia, 23 days for Delusional Disorder, 30 days for Bipolar Disorder and 19 days in Schizoaffective Disorder.

**CONCLUSIONS:** Our analysis identified two main patterns of drug switching, the most frequent being “tapering and overlap” in oral treatment, followed by “immediate switch” in patients treated with LAIs.

Although our patients are unlike many of those enrolled in clinical trials, the present study indicates that the predominant switching strategies conforms with the Safety Data Sheet.

## 67

### Effects of Long-term Valbenzine on Psychiatric Status in Patients with Tardive Dyskinesia and a Primary Mood Disorder

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