Baseline Demographics and Clinical Characteristics From OASIS: Observational Study of Long-Acting Injectables in Schizophrenia

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INTRODUCTION

- Atypical long-acting injectable (aLAI) antipsychotic medications are beneficial treatments for schizophrenia,[1,2] but there are gaps in the understanding of their role, especially in real-world clinical settings
- The Observational Study of Long-Acting Injectables in Schizophrenia (OASIS; NCT03919994) was an assessment of real-world treatment patterns and clinical, socioeconomic, and patient-reported outcomes in patients with schizophrenia initiating an aLAI antipsychotic

OBJECTIVE

- To present baseline OASIS participant demographics and clinical characteristics
  - Please see accompanying posters 161 and 163 for details on treatment patterns and outcomes, respectively, from OASIS

METHODS

Study Design

- OASIS was a prospective, noninterventional, multicenter cohort study assessing real-world experience of adult patients with schizophrenia who were initiated on 1 of 4 aLAI antipsychotics: aripiprazole lauroxil, aripiprazole monohydrate, paliperidone palmitate, or risperidone LAI
  - Patients could be initiated on an aLAI antipsychotic treatment in an inpatient or outpatient setting
  - Because of its small size, the risperidone LAI group (n=9) was not included in presentations of study results (here and in posters 161 and 163)
- Patients were enrolled following clinician decision to initiate an aLAI antipsychotic
  - Treatment was given at the discretion of the clinician and with patient consent
- Patients were followed for up to 12 months; the clinician determined visit frequency and any procedures
- Assessments were completed at regularly scheduled visits according to the clinician's plan of care

Study Population

Key Inclusion Criteria

- Adults aged ≥18 years with a clinician's diagnosis of schizophrenia
- No treatment with an aLAI antipsychotic in the 6 months before baseline assessment
- Patients must either be known to the site or, if new, must be deemed likely to continue to engage in treatment at the site

Key Exclusion Criteria

- Current or planned participation in an interventional clinical study or participation in an interventional clinical study within 30 days before enrollment

Assessments and Analysis

- Baseline demographics and clinical characteristics
- Key outcomes assessed over 12 months of follow-up included the following:
  - Patterns of aLAI antipsychotic use, including the number of, timing of, and reasons for treatment switches and discontinuations
  - Socioeconomic characteristics, including changes to employment and insurance status
  - Clinical illness and symptom severity
    - The Clinical Global Impressions–Severity scale—a clinician-rated assessment of mental illness severity scored on a scale of 1 (normal, not at all ill) to 7 (most extremely ill)
    - *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*, Clinician-Rated Dimensions of Psychosis Symptom Severity—an 8-item measure capturing the severity of psychosis symptom dimensions, including hallucinations, delusions, disorganized speech, abnormal psychomotor behavior, negative symptoms, impaired cognition, depression, and mania, scored on a scale of 0 (not present) to 4 (present and severe)[3]
  - Patient-reported outcomes
    - Glasgow Antipsychotic Side-Effect Scale (GASS)[4]
    - Sexual function questionnaire (supplement to the GASS)

Statistical Analysis

- Summary statistics (means [SD], numbers, and proportions) are presented for baseline participant demographics and clinical characteristics

RESULTS

- Among the 277 patients with schizophrenia enrolled in OASIS, most were male, White, unemployed, and insured by Medicaid or Medicare (**Table 1**)
- Most enrolled patients came from a community health clinic or private practice site, from an urban setting, and from the southern United States (**Table 2**)
- Baseline severity of illness was moderate with a CGI-S score of 4.21 (**Table 3**)
  - Comorbid anxiety, depression, and/or history of substance use disorder were common among participants
- Overall, 20.6% of patients had ≥1 schizophrenia-related emergency department visit in the 12 months before baseline, and 63.2% had ≥1 schizophrenia-related outpatient visit (**Table 4**)
- Oral antipsychotics were the most common treatment in the 12 months before enrollment in OASIS (**Table 5**)
  - Most patients initiated their aLAI antipsychotic as outpatients

Table 1. Demographic Characteristics

Characteristic	Total[a] (N=277)	Aripiprazole lauroxil (n=96)	Aripiprazole monohydrate (n=61)	Paliperidone palmitate (n=111)
Age, mean (SD), years	**37.7 (14.9)**	39.0 (15.5)	37.6 (15.4)	36.0 (14.0)
Male, n (%)	**182 (65.7)**	62 (64.6)	41 (67.2)	73 (65.8)
White, n (%)	**131 (47.3)**	54 (56.3)	26 (42.6)	45 (40.5)
Unemployed, n (%)	**147 (53.1)**	44 (45.8)	33 (54.1)	66 (59.5)
Insurance status,[b,c,d] n (%)				
Uninsured	**37 (13.4)**	5 (5.2)	15 (24.6)	16 (14.4)
Insured	**231 (83.4)**	87 (90.6)	44 (72.1)	92 (82.9)
Medicaid	**130 (46.9)**	54 (56.3)	22 (36.1)	49 (44.1)
Medicare	**84 (30.3)**	32 (33.3)	16 (26.2)	30 (27.0)
Private insurance	**40 (14.4)**	14 (14.6)	11 (18.0)	15 (13.5)
Single, n (%)	**209 (75.5)**	77 (80.2)	42 (68.9)	85 (76.6)
Lives with family, n (%)	**149 (53.8)**	55 (57.3)	25 (41.0)	63 (56.8)
Challenges accessing outpatient care, n (%)	**99 (35.7)**	29 (30.2)	23 (37.7)	40 (36.0)
Reason for challenges,[d] n (%)				
Travel to site	**60 (60.6)**	19 (65.5)	15 (65.2)	21 (52.5)
Payment for visit	**18 (18.2)**	3 (10.3)	5 (21.7)	7 (17.5)
Help needed to get to visit	**54 (54.5)**	18 (62.1)	8 (34.8)	26 (65.0)
Other[e]	**17 (17.2)**	3 (10.3)	4 (17.4)	9 (22.5)

[a]Total N includes the patients in the risperidone LAI group (n=9), which is not shown because of low enrollment.
[b]Unknown/not reported, missing response, and other (n=33).
[c]Includes responses such as the Affordable Care Act or similar programs (n=15).
[d]Multiple responses allowed.
[e]Includes childcare difficulties, getting medication approved, medication delivery delays, and other travel issues.
LAI, long-acting injectable; SD, standard deviation.

Table 2. Location-of-Care Characteristics

Characteristic	Total[a] (N=277)	Aripiprazole lauroxil (n=96)	Aripiprazole monohydrate (n=61)	Paliperidone palmitate (n=111)
Region, n (%)				
South	**142 (51.3)**	40 (41.7)	37 (60.7)	56 (50.5)
West	**61 (22.0)**	24 (25.0)	12 (19.7)	25 (22.5)
Midwest	**45 (16.2)**	10 (10.4)	10 (16.4)	25 (22.5)
Northeast	**29 (10.5)**	22 (22.9)	2 (3.3)	5 (4.5)
Type of site,[b,c] n (%)				
Community mental health clinic	**128 (46.2)**	27 (28.1)	34 (55.7)	66 (59.5)
Independent or private practice	**125 (45.1)**	64 (66.7)	17 (27.9)	40 (36.0)
Academic center	**15 (5.4)**	2 (2.1)	2 (3.3)	11 (9.9)
Hospital network	**29 (10.5)**	6 (6.3)	6 (9.8)	17 (15.3)
Other	**9 (3.2)**	0	3 (4.9)	6 (5.4)
Site location type,[d] n (%)				
Urban	**168 (60.6)**	42 (43.8)	34 (55.7)	87 (78.4)
Suburban	**83 (30.0)**	46 (47.9)	19 (31.1)	18 (16.2)
Rural	**12 (4.3)**	6 (6.3)	1 (1.6)	5 (4.5)

[a]Total N includes the patients in the risperidone LAI group (n=9), which is not shown because of low enrollment.
[b]Multiple responses allowed.
[c]The study protocol was amended to include locations of care that treated inpatients who initiated an aLAI antipsychotic.
[d]Not reported (n=14).
aLAI, atypical long-acting injectable.

Table 3. Baseline Clinical Characteristics

Characteristic	Total[a] (N=277)	Aripiprazole lauroxil (n=96)	Aripiprazole monohydrate (n=61)	Paliperidone palmitate (n=111)
CGI-S score,[b] mean (SD)	**4.21 (1.1)**	4.19 (1.0)	4.08 (1.2)	4.36 (1.1)
Time since schizophrenia diagnosis,[c] mean (SD), years	**11.9 (12.5)**	12.5 (11.4)	10.98 (12.3)	11.7 (13.4)
Comorbid mental health–related conditions,[d] n (%)				
Anxiety	**70 (25.3)**	31 (32.3)	9 (14.8)	28 (25.2)
Depression	**66 (23.8)**	27 (28.1)	16 (26.2)	21 (18.9)
History of substance use disorder,[e] n (%)	**121 (43.7)**	28 (29.2)	34 (55.7)	56 (50.5)

[a]Total N includes the patients in the risperidone LAI group (n=9), which is not shown because of low enrollment.
[b]Score of 4 corresponds to "moderately ill," while a score of 3 corresponds to "mildly ill."
[c]Available for 240 patients.
[d]Ongoing at baseline.
[e]Includes alcohol, marijuana, methamphetamine, stimulant, opioid, and other use disorders.
CGI-S, Clinical Global Impressions-Severity; LAI, long-acting injectable; SD, standard deviation.

Table 4. Healthcare Resource Use in the 12 Months Before Baseline

Characteristic	Total[a] (N=277)	Aripiprazole lauroxil (n=96)	Aripiprazole monohydrate (n=61)	Paliperidone palmitate (n=111)
≥1 schizophrenia-related ED visit, n (%)	**57 (20.6)**	15 (15.6)	10 (16.4)	30 (27.0)
ED visits per patient, mean (SD)	**1.4 (0.7)**	1.3 (0.7)	1.5 (0.7)	1.4 (0.8)
≥1 schizophrenia-related inpatient visit, n (%)	**111 (40.1)**	27 (28.1)	30 (49.2)	52 (46.9)
Inpatient visits per patient, mean (SD)	**1.4 (0.7)**	1.4 (0.7)	1.4 (0.7)	1.3 (0.6)
Length of inpatient stay, mean (SD), days	**15.2 (28.4)**	14.8 (19.8)	23.7 (49.3)	11.0 (9.0)
≥1 schizophrenia-related outpatient visits, n (%)	**175 (63.2)**	50 (52.1)	40 (65.6)	76 (68.5)
Outpatient visits per patient, mean (SD)	**9.1 (26.5)**	14.3 (47.4)	6.9 (11.6)	7.2 (7.5)

[a]Total N includes the patients in the risperidone LAI group (n=9), which is not shown because of low enrollment.
ED, emergency department; LAI, long-acting injectable; SD, standard deviation.

Table 5. Antipsychotic Use in 12 Months Before Baseline and aLAI Administration Setting

Characteristic	Total[a] (N=277)	Aripiprazole lauroxil (n=96)	Aripiprazole monohydrate (n=61)	Paliperidone palmitate (n=111)
Antipsychotic use in the prior 12 months, n (%)	**96 (34.7)**	24 (25.0)	21 (34.4)	47 (42.3)
aLAI antipsychotics, n (%)	**7 (7.3)**	2 (8.3)	1 (4.8)	4 (8.5)
Oral antipsychotics, n (%)	**93 (96.9)**	23 (95.8)	21 (100)	45 (95.7)
Setting of first aLAI antipsychotic administration,[b] n (%)				
Outpatient	**177 (63.9)**	63 (65.6)	41 (67.2)	70 (63.1)
Inpatient	**33 (11.9)**	5 (5.2)	6 (9.8)	21 (18.9)
Board and care	**7 (2.5)**	1 (1.0)	3 (4.9)	2 (1.8)
Other	**3 (1.1)**	1 (1.0)	1 (1.6)	1 (0.9)

[a]Total N includes the patients in the risperidone LAI group (n=9), which is not shown because of low enrollment.
[b]Not reported (n=57).
aLAI, atypical long-acting injectable.

LIMITATIONS

- Because of the nonrandomized, observational design of OASIS, characteristics were evaluated descriptively, and no statistical comparisons were conducted
- Overall sample size was lower than anticipated in part because of challenges associated with the COVID-19 pandemic
- The baseline characteristics observed among enrolled patients may not be generalizable to the larger population of people living with schizophrenia who are treated with an aLAI antipsychotic
- The study did not include data on older conventional LAI antipsychotics (eg, haloperidol decanoate, fluphenazine decanoate) or other aLAI antipsychotics that became available during or after the study period

CONCLUSIONS

- This cohort of 277 adult patients with schizophrenia being treated with aLAIs in a real-world setting were identified and followed for up to 12 months in the OASIS study
- Prospectively collected data on treatment patterns and healthcare resource use from the OASIS cohort are reported in posters 161 and 163 at this meeting, respectively
- Results from the OASIS study will fill important gaps in real-world research on aLAI antipsychotic use to date, reflecting use of these agents in patients with moderate symptoms of schizophrenia who initiated aLAI antipsychotics as outpatients in community and private practice clinics

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AUTHOR DISCLOSURES

LNS, MJD, CA, and **JAM** are or were employees of Alkermes, Inc., and may own stock/options in the company.

PJW is a former employee of Alkermes and has been a consultant for Alkermes, Lyndra, MapLight, and Teva.

EDA has consulted or served on advisory boards for Alkermes, Atheneum, Janssen, Karuna, Lundbeck/Otsuka, Neurocrine Biosciences, Roche, Sunovion, and Teva and has received research funding from Alkermes, Astellas, Biogen, Boehringer Ingelheim, CMS, InnateVR, Janssen, National Network of Depression Centers, Neurocrine Biosciences, Novartis, Otsuka, Pear Therapeutics, and Takeda.

PDH has received fees for consulting and travel from Alkermes, BioXcel, Boehringer Ingelheim, Karuna, Minerva, and Sunovion; royalties for Brief Assessment of Cognition in Schizophrenia (owned by VeraSci, Inc.); and grant support from Stanley Medical Research Foundation and Takeda; and is chief scientific officer with i-Function, Inc.

JMK has been a consultant for or received honoraria from Alkermes, Boehringer Ingelheim, Click Therapeutics, Intra-Cellular Therapies, Janssen, Johnson and Johnson, Karuna, LB Pharmaceuticals, Lundbeck, Lyndra, Merck, Neurocrine Biosciences, Newron, Otsuka, Pierre Fabre, Reviva, Roche, Saladax, Sunovion, Takeda, and Teva Pharmaceutical Industries; has received grant support from Janssen, Lundbeck, and Otsuka; and is a shareholder of LB Pharmaceuticals and Vanguard Research Group.

SRS is an employee of The University of Texas at Austin College of Pharmacy; was appointed to the Texas Health and Human Services Commission, San Antonio State Hospital, and UT Health San Antonio Long School of Medicine; has consulted for Alkermes, BioXcel, Genomind, Janssen, Karuna, and Otsuka; has participated on speakers bureaus for BioXcel, Otsuka PsychU, Neurocrine, Teva, Texas Society of Health-System Pharmacists, and several professional organizations; serves on the Business Development Council for the College of Psychiatric and Neurologic Pharmacists; has served as a defendant and plaintiff expert witness; and has no direct stock ownership in any pharmaceutical corporation.

JT was an employee of Worldwide Clinical Trials at the time of the study.

DIV has served as a consultant for and has received research grant funding from Alkermes; has served as a consultant, speaker, and advisory board participant for Otsuka; has served as a consultant and speaker for Janssen; and has served as an advisory board participant for Lyndra.

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