- for discontinuation



Characteristics	4 weeks ENLIGHTEN-1 (N=134)	3 months ENLIGHTEN-EARLY (N=211)	6 months ENLIGHTEN-2 (N=274)	1 year ENLIGHTEN-1-EXT (N=277)	Eľ
Age, mean (SD), years	40.8 (12.6)	26.0 (6.1)	40.3 (9.8)	41.4 (11.3)	
Male, n (%)	85 (63.4)	142 (67.3)	193 (70.4)	161 (58.1)	
Race, n (%)					
White	87 (64.9)	139 (65.9)	63 (23.0)	218 (78.7)	
Black	42 (31.3)	62 (29.4)	199 (72.6)	52 (18.8)	
Weight, mean (SD), kg	77.9 (15.4)	71.6 (13.3)	77.2 (13.7)	79.1 (17.8)	
BMI, mean (SD), kg/m <sup>2</sup>	26.3 (4.5)	23.8 (3.3)	25.4 (3.1)	26.9 (5.1)	
CGI-S, <sup>a</sup> mean (SD)	5.1 (0.7)	3.9 (0.8)	3.5 (0.6)	3.9 (1.0)	

<sup>a</sup>From the full analysis set for ENLIGHTEN-1 (N=132), ENLIGHTEN-EARLY (N=202), ENLIGHTEN-2 (N=266), and ENLIGHTEN-1-EXT (N=248) and the safety population for ENLIGHTEN-2-EXT and the 4-Year Open-Label study. BMI, body mass index; CGI, Clinical Global Impressions–Severity; EXT, extension

3.1 (0.7)

3.1 (0.9)

# Study Retention Rates in the Olanzapine/Samidorphan Phase 3 Clinical Program

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OLZ/SAM, combination olanzapine and samidorphan; EXT, extension

## Table 2. Reasons for Discontinuation Among Patients on OLZ/SAM Treatment

4 weeks ENLIGHTEN-1 (N=134)	3 months ENLIGHTEN- EARLY (N=211)	6 months ENLIGHTEN-2 (N=274)	1 year ENLIGHTEN-1- EXT (N=277)	1 year ENLIGHTEN-2- EXT (N=265)	4 years Open-Label Study (N=523)
8 (6.0)	20 (9.5)	23 (8.4)	43 (15.5)	36 (13.6)	133 (25.4)
2 (1.5)	10 (4.7)	33 (12.0)	16 (5.8)	15 (5.7)	44 (8.4)
1 (0.7)	0	2 (0.7)	5 (1.8)	1 (0.4)	1 (0.2)
1 (0.7)	11 (5.2)	22 (8.0)	19 (6.9)	22 (8.3)	37 (7.1)
0	NA	8 (2.9)	8 (2.9)	12 (4.5)	0
NA	NA	NA	NA	NA	5 (1.0)
0	0	1 (0.4)	1 (0.4)	2 (0.8)	2 (0.4)
0	3 (1.4)	1 (0.4)	1 (0.4)	8 (3.0)	20 (3.8)
0	0	0	0	0	1 (0.2)
0	2 (0.9)	8 (2.9)	1 (0.4)	2 (0.8)	92 (17.6) <sup>b</sup>

<sup>a</sup>Patients discontinued treatment, but their reasons for doing so were not collected. <sup>b</sup>Overall, 72 patients discontinued the study due to the Ukraine-Russia conflict.

• Please see the primary publications for the limitations inherent to each study<sup>2-7</sup>

• Differences in retention could be related to the different designs of the individual studies (eg, double-blind versus open label) • These results may not be generalizable to all patients with schizophrenia or bipolar I disorder

• In the 4-year open-label study, retention rates were 53.7% at 2 years and 32.5% at 4 years

• Withdrawal by subject was the most common reason for discontinuation from each study, except for the 6-month trial (adverse event)

6. Kahn RS, et al. J Clin Psychiatry. 2023;84(3):22m14674. DOI: <u>10.4088/JCP.22m14674</u>

- 7. Ballon JS, et al. Presented at: Annual Meeting of the American Psychiatric Association; May 4-8, 2024; New York, NY.
- 8. Cutler AJ, et al. Presented at: Psych Congress; October 29–November 2, 2024; Boston, MA.
- 9. Jain R, et al. Presented at: Psych Congress; October 29–November 2, 2024; Boston, MA.

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