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Supplementary Material

Article Title: Olanzapine Plus Samidorphan (ALKS 3831) in Schizophrenia and Comorbid Alcohol Use Disorder: A Phase 2, Randomized Clinical Trial

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Supplementary Table 1. Change from baseline in WHO drinking risk^a at Week 24 of the double-blind treatment period (ITT population)

Baseline WHO drinking risk category	Improvement from baseline	OLZ/SAM^b n/N (%)	Olanzapine^b n/N (%)
Abstinence	N/A	3/3 (100.0)	6/6 (100.0)
Low risk	≥1 level	7/46 (15.2)	5/49 (10.2)
Medium risk	≥1 level	24/34 (70.6)	18/28 (64.3)
	≥2 level ^c	7/34 (20.6)	2/28 (7.1)
High risk	≥1 level	8/13 (61.5)	15/24 (62.5)
	≥2 level ^c	2/13 (15.4)	8/24 (33.3)
Very high risk	≥1 level	6/15 (40.0)	6/9 (66.7)
	≥2 level ^c	2/15 (13.3)	4/9 (44.4)

n, number of patients meeting criteria; N, number of patients with assessment

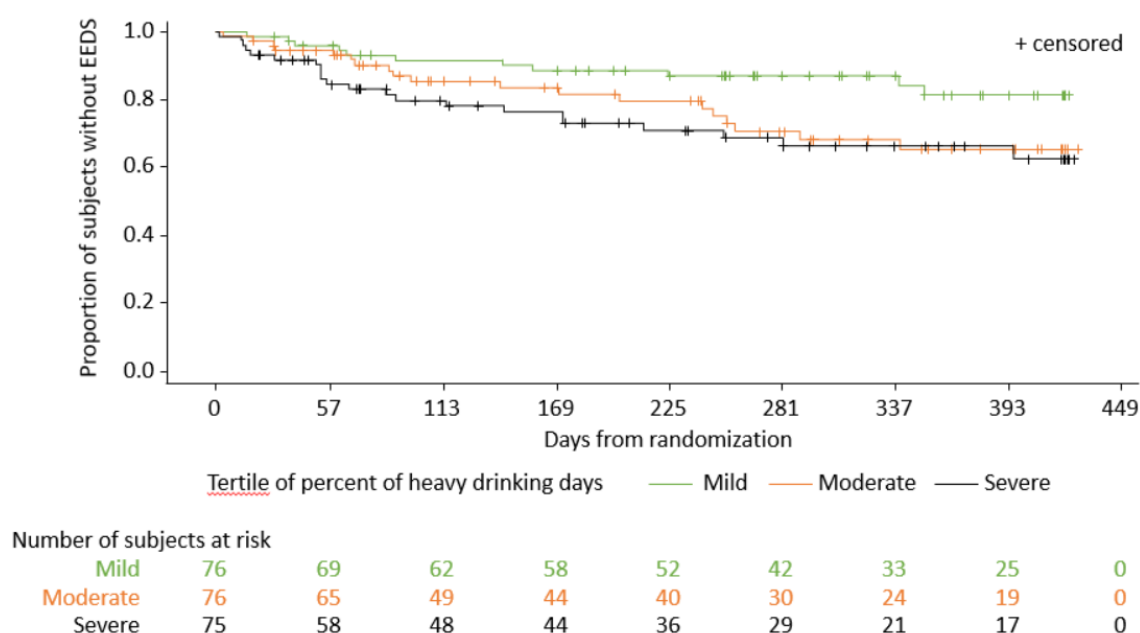
^aAt each visit, alcohol consumption per day was calculated based on the number of drinks per day as follows: alcohol consumption per day = total number of drinks × 14 grams (g)/total number of days. WHO drinking risk levels were defined according to alcohol consumption (g) per drinking day: abstinence (0 g); low risk (males 1–40 g, females 1–20 g); medium risk (males 41–60 g, females 21–40 g); high risk (males 61–100 g, females 41–60 g); very high risk (males ≥101 g, females ≥61 g)^{31, 32}

^bOne patient receiving olanzapine (low risk at baseline) and one patient receiving OLZ/SAM (medium risk at baseline) did not have post-baseline TLFB measurement available

^cThe n numbers for a ≥2 level improvement are also included in the n numbers for ≥1 level improvement

ITT, intention to treat; N/A, not applicable; OLZ, olanzapine; PBO, placebo; SAM, samidorphan 10 mg; TLFB, timeline follow-back; WHO, World Health Organization

Supplementary Figure 1. Kaplan–Meier plot of time to first EEDS by percent of HDDs during the double-blind treatment period (ITT population)^a



^aHeavy drinking (severe) was associated with earlier time to EEDS events compared to mild drinking (HR: 2.53; 95% CI: 1.23, 5.23; $P=.012$)

“+” indicates when the subject is censored (subject discontinued without developing the event of analysis); CI, confidence interval; ITT, intention to treat; EEDS, exacerbation of disease symptoms; HDD, heavy drinking day; HR, hazard ratio