The following abstracts were presented as posters at the 2019 NEI Congress

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https://doi.org/10.1017/S1092852920001297 Published online by Cambridge University Press

CNS Spectrums (2020), **25**, 265–321. © Cambridge University Press 2020
doi:10.1017/S1092852920000188

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3rd:
A Marionettist Pulling My Strings: A Case Of Buprenorphine-induced Chorea (#131)

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Olanzapine/Samidorphan for Schizophrenia: Weight Gain and Metabolic Outcomes in Phase 3 ENLIGHTEN-2 and Subsequent Long-Term, Open-Label Safety Study

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ABSTRACT: Background: Opioid antagonists may mitigate medication-associated weight gain and/or metabolic dysregulation. ENLIGHTEN-2 evaluated a combination of olanzapine and the opioid antagonist samidorphan (OLZ/SAM) vs olanzapine for effects on weight gain and metabolic parameters over 24 weeks in adults with stable schizophrenia.

METHODS: This phase 3, double-blind study (ClinicalTrials.gov: NCT02694328) enrolled adults 18–55 yo with stable schizophrenia, randomized 1:1 to once-daily OLZ/SAM or olanzapine. Co-primary endpoints were percent change from baseline in body weight and proportion of patients with ≥10% weight gain at week 24. Waist circumference and fasting metabolic parameters were also measured. Completers could enter a 52-week open-label safety extension.

RESULTS: 561 patients were randomized: 550 were dosed, 538 had ≥1 post-baseline weight assessment, and 352 (64%) completed; 10.9% discontinued due to AEs. At week 24, least squares mean (SE) percent weight change from baseline was 4.21 (0.68)% with OLZ/SAM and 6.59 (0.67)% with olanzapine (difference, −2.38 [0.76]%; P=0.003). Fewer patients treated with OLZ/SAM (17.8%) had ≥10% weight gain vs olanzapine (29.8%; odds ratio=0.50; P=0.003). The change from baseline in waist circumference was significantly smaller with OLZ/SAM (P<0.001). Common AEs (≥10%) with OLZ/SAM and olanzapine were weight increased (24.8%, 36.2%), somnolence (21.2%, 18.1%), dry mouth (12.8%, 8.0%), and increased appetite (10.9%, 12.3%), respectively. Metabolic parameter changes were generally small and remained stable with long-term OLZ/SAM treatment.

DISCUSSION: OLZ/SAM treatment limited weight gain associated with olanzapine. Metabolic parameter changes were generally small, similar between groups over 24 weeks, and remained stable over an additional 52 weeks of open-label OLZ/SAM treatment.
Funding Acknowledgements: This study was funded by Alkermes, Inc.