

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

The 2019 NEI Congress would like to congratulate the following scientific poster winners:

**1st:**

Implementation Of Personalized Medicine In A Community Psychiatry Practice (#110)

**2nd:**

Comparison Of Traditional Therapy Versus Biofeedback For Tension Type And Migraine Headaches A One Year Retrospective Study Of 50 Patients (#189)

**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  $\geq 10\%$  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  $\geq 1$  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  $\geq 10\%$  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 ( $\geq 10\%$ ) 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.

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