CGI-S and SDS at Day 28 (0.75), moderate SES (0.66), with suggested MCT ranging from 3 to 7 with an MCT value of 5 pts. CDF curves from TRANSFORM-2 showed clear separation between the ESK+AD vs AD+PBO across a number of responder definitions inclusive of those identified with the anchor-based analyses.

CONCLUSIONS: The current study is the first to derive an MCT on the PHQ-9 and SDS in TRD to measure meaningful change from the perspective of the patient using regulatory-preferred psychometric anchor-based methodology. These analyses assist with interpretation of meaningfulness of esketamine phase 3 clinical trial results from the patient perspective.

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Treating Chronic Pain and Preventing Opioid Use Disorders in the Underserved: An Integrated Primary Care Model

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ABSTRACT: This poster builds on the CDC pain management guidelines and the current ASAM recommendations for substance use assessment to build an integrated primary care model for holistic chronic pain management in an urban, underserved primary care clinic. Using a case from our Federally Qualified Health Care Center, which operates in a southwest Denver clinic, a program of integrated care assessment, diagnosis, and holistic treatment planning is outlined for this client with chronic pain, physical, and behavioral health issues. Using a comprehensive care approach for complex clients, which are typical presentations for urban, underserved clients, we discuss the utilization of best practices in medication management for chronic pain (Alternatives to Opioids (ALTOS), prescribed and complementary and alternative practices (e.g., PT, acupuncture, etc), and behavioral health services (psychiatric assessment and treatment, psychotherapy, support groups, etc) to improve outcomes for our clients.

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Single-Dose Pharmacokinetics of Amphetamine Extended-Release Tablet Compared with Amphetamine Extended-Release Oral Suspension

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ABSTRACT: Objectives: Evaluate comparative bioavailability of single-dose amphetamine extended-release tablet (AMPH ER TAB, Tris Pharma, Inc., Monmouth Junction, NJ) 20 mg, swallowed whole or chewed and amphetamine extended-release oral suspension (AMPH EROS) 2.5 mg/mL; and evaluate whether a PK food effect exists on AMPH ER TAB (contains a 3.2:1 ratio of d- to l-amphetamine).

METHODS: Healthy volunteers (18-55 yr) were randomized to 1 dose of AMPH ER TAB 20 mg swallowed (fasted), chewed (fed/fasted), or 20 mg AMPH EROS (fasted).
A crossover design was used. Samples were collected each period pre-dose and at time points to 60 h post-dose. D-and l-amphetamine were measured, and PK was calculated (90% CIs of the ratios of the geometric mean plasma levels) for Cmax, AUCt, and AUC0∞. Comparative bioavailability was determined when ratios were within 80 and 125%. Safety was also assessed.

RESULTS: 32 subjects completed the study. Based on the calculated bioavailability ratios, for AMPH ER TAB swallowed vs. AMPH EROS fasted: d-amphetamine total and peak exposures were found to be similar: AUC0-t: 100.68-108.08%, AUC0-∞:101.47-109.52%, Cmax: 98.10-103.17%. For l-amphetamine, the total and peak exposures were similar: AUC0-t: 100.31-108.57%, AUC0-∞:101.27-111.09%, Cmax: 98.2-103.37%.
AMPH ER TAB chewed vs. AMPH EROS fasted: For d-amphetamine, the total and peak exposures were similar: AUC0-t: 99.23-106.62%, AUC0-∞: 99.58-107.59%, Cmax: 99.91-105.14%. For l-amphetamine, the total and peak exposure was similar: AUC0-t: 98.16-106.35%, AUC0-∞: 98.44-108.11%, Cmax: 99.53-104.75%.
Food effect: AMPH ER TAB, chewed, fasted vs. fed: For d-amphetamine, the total and peak exposure was similar: AUC0-t: 92.57-99.49%, AUC0-∞: 91.12-98.48%, Cmax: 94.22-99.17%.
For l-amphetamine, the total and peak exposure was similar: AUC0-t: 91.27-98.91%, AUC0-∞: 88.44-97.17%, Cmax: 94.52-99.50%).
No serious AEs were reported during the conduct of this study, and the AE profiles were observed to be similar in frequency of events and severity to other amphetamine formulations used in ADHD.

CONCLUSIONS: Bioavailability of single dose of AMPH ER TAB for both d- and l-amphetamine was comparable, swallowed whole or chewed, to an equivalent 20 mg dose of the reference product AMPH EROS, 2.5 mg/mL fasted, and showed equivalent peak and overall exposure.

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