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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No food effect was observed for AMPH ER TAB administered chewed. All AEs were mild in severity and AE profiles were similar to other amphetamine formulations used for treatment of ADHD.
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Palatability Assessment of a New Amphetamine Extended-Release Tablet Formulation

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ABSTRACT: Background: In 2016, the US FDA issued an industry guidance document "Quality Attribute Considerations for Chewable Tablets" which describes the quality attributes to be considered when developing chewable tablets. It includes recommendations on selection of acceptance criteria for measuring palatability (having a taste acceptable to the patient or has adequate masking). These data are now recommended as part of ANDA submissions. Palatability is a known positive contributing factor to drug adherence and persistence. We summarize here palatability data for a new amphetamine extended-release tablet (Dyanavel XR® Extended Release Tablet; AMPH ER TAB).

METHODS: This was a 2-arm preplanned secondary analysis from a comparative bioavailability study: single-dose AMPH ER TAB 20 mg chewed under fasting (Treatment A) and fed (Treatment B) conditions. Subjects rated the palatability of AMPH ER TAB (Treatments A+B) through a 5-question palatability questionnaire. The questions included in the palatability questionnaire were as follows:

1. Oral sensation/mouth feel of the drug product
2. Taste of the drug product
3. How strong is the taste?
4. Aftertaste of the product
5. How strong is the aftertaste?

Subjects completed the questionnaire within 10 minutes from the time of drug administration, which was evaluated and scored according to the rubric below:
Q1, Q2, Q4: palatability- Very unpleasant (score of 1), Unpleasant (2), No sensation or mouthfeel (3), Pleasant (4), and Very pleasant (5)
Q3, Q5 (Taste/aftertaste strength): Very strong (score of 1), Strong (2), Moderate (3), Mild (4), No aftertaste (5).
Scores of 1-2 for both categories were Negative; score of 3 was Neutral, and 4-5 were Positive.

RESULTS: 35 subjects comprised the palatability dataset (completed one question on the questionnaire). In the palatability analysis, for treatments A and B, most of the subjects rated the oral sensation/mouth feel of AMPH ER TAB (Question 1) and the taste of AMPH ER TAB (Question 2) as positive (pleasant to very pleasant) (70.1% and 83.6%, respectively). When evaluating taste strength (Question 3): 43.3% rated the strength as positive (mild/no taste) and 43.3% of subjects rated the strength as neutral (moderate taste). Also, 82.1% rated the aftertaste of AMPH ER TAB (Question 4) as positive (pleasant/very pleasant) and 52.2% rated the strength of the aftertaste as positive (mild/no taste).

CONCLUSION: Most subjects rated the oral sensation and taste as pleasant or very pleasant, whether chewed under fasted conditions or after a meal. With respect to the taste strength, most subjects rated it as moderate (chewed under fasted conditions) or mild/no taste (chewed after a meal). Aftertaste was rated as pleasant or very pleasant in most subjects, with the strength as moderate (chewed under fasted conditions) or mild/no aftertaste (chewed after a meal). AMPH ER Tablets provided an overall pleasant taste and mouthfeel experience for patients.
Funding Acknowledgements: Tris Pharma, Inc.

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Improvement of Sexual Function Observed During Treatment of Major Depressive Disorder with Adjunctive Pimavanserin

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