includes patients with primary diagnosis of MDD, have previously received at least 20 TMS treatments and must be evaluated with at least two clinical rating scales that were entered each day during treatment.

RESULT:

Number of treated patients:	68
Patients responded to treatment:	50 (73.5%)
Patients not responded:	18 (26.4%)
Mean # of treatments received:	37
Mean Baseline PHQ-9 Score:	19
Mean Outcome PHQ-9 Score:	7

To evaluate the cause of treatment failure in 18 non-responsive patients, patient charts were reviewed in detail. Patients were interviewed near the end of treatment, during follow-ups, and over the phone. It was established that they were either misdiagnosed, have symptoms of other psychiatric disorders such as bipolar depression, have dual diagnoses (e.g. MDD with anxiety, OCD, PTSD) or unclear diagnoses and in need of further psychiatric evaluations. The variety of these diagnostic scenarios mentioned are not typically treated with TMS therapy or treated differently with TMS as compared to MDD, hence the explanation of therapy failure.

CONCLUSION: Number one cause of TMS treatment failure is misdiagnosis due to various reasons. That includes failure to be accurately diagnosed by a primary psychiatrist, as those patients did not have primary psychiatrist and were referred by primary care physicians and were getting treated for MDD without a proper psychiatric evaluation and diagnosis. However, due to the limitations of the study due to small sample size, we propose that further investigations are needed to be replicated in larger patient population.

81 Bioequivalence of a Manipulation-Resistant Immediate-Release Amphetamine Sulfate Formulation Compared with Reference Standard

Steve Caras, PhD¹; and Terrilyn Sharpe²

 Vice President Clinical Development, Arbor Pharmaceuticals, LLC, Atlanta, GA, USA
 Director of Clinical Development, Arbor Pharmaceuticals, LLC, Atlanta, GA, USA

ABSTRACT: Study Objectives: We compared the bioavailability of racemic amphetamine (d-amphetamine and l-amphetamine) from a manipulation-resistant immediate-release (IR) amphetamine sulfate capsule

(AR19) versus amphetamine sulfate IR tablets (reference).

METHOD: In this open-label, randomized, two-period, two-treatment, two-sequence, crossover study, 36 healthy volunteers aged 18–45 received a single dose (20-mg capsule) of AR19 in one period and a single dose (2 x 10-mg tablets) of reference in another period, after a 10-hour overnight fast. Each drug administration was separated by a washout period of at least 6 days. Bioequivalence for d- and l-amphetamine was assessed using time to peak concentration (Tmax), peak concentration in plasma (Cmax), and area under the plasma concentration—time curve from time-zero to the time of the last quantifiable concentration (AUClast) and extrapolated to infinity (AUCinf).

RESULTS: All 36 volunteers completed both treatment sequences. Mean (standard deviation; SD) Tmax for dand l-amphetamine was similar for AR19 (2.84 [1.05]; 3.05 [1.22], respectively) and reference (2.52 [0.75]; 2.75 [1.00], respectively). The geometric least-squares mean ratios and 90% confidence intervals were within the boundary of 80%-125% for bioequivalence for Cmax (d-amphetamine, 98.35% [96.12-100.64]; l-amphetamine, 98.82% [96.42-101.28]), AUClast (d-amphetamine, 99.45% [96.92-102.05]; l-amphetamine, 99.29% [96.55–102.10]), AUCinf and (d-amphetamine, 99.50% [96.77–102.30]; l-amphetamine, [96.06-102.50]). A total of 13 mild adverse events were reported by 7 volunteers (AEs; AR19, n = 5; reference, n = 8). No serious AEs were reported.

CONCLUSION: AR19 was well tolerated and was bioequivalent to reference when administered as a 20-mg dose in healthy volunteers.

Funding Acknowledgements: This study was funded by Arbor Pharmaceuticals, LLC.

82 Ice Melts Phantogeusia: Cold Inhibition of Gustatory Hallucinations

Suhanna Mutti¹; and Alan R. Hirsch, MD²

¹ Medical Student, Aureus University School of Medicine, Oranjestad, Aruba

² Medical Director, Smell and Taste Treatment and Research Foundation, Chicago, IL

ABSTRACT: Introduction: Relief of phantogeusia through ice cube stimulation has not heretofore been noted.

METHODS: This 70-year-old left handed (familial) female noted the onset, three and a half years ago, of reduced taste