that <17% of Major Depressive Disorder (MDD) patients respond to novel oral treatments after two prior antidepressant failures. To address this low response rate and continue to investigate the use of patient-rated outcomes in clinical trials, an antidepressant with a new mechanism of action is being investigated for efficacy and safety utilizing both clinician-rated and patient-reported scales.

METHODS: This is a post-hoc analysis of a Janssen R&D Phase 2a clinical trial (ESKETINTRD2003). Subjects aged 20-64 withMDD without psychotic features (DSM IV) and a history of inadequate response to ≥2 antidepressants were randomized [3:1:1:1] to 1 week of twice-weekly treatment with intranasal placebo (n = 33), esketamine 28 mg (n = 11), 56 mg (n = 11), or 84 mg (n = 12). Participants taking oral antidepressants at study entry continued treatment during the study. Changes in depression severitywere measured using the Clinical Global Impression Severity (CGI-S) and the Patient Global Impression Severity (PGI-S) scales.

RESULTS: At all esketamine doses (28 mg, 56 mg, 84 mg), subjects reported a one-point mean change in PGI-S from baseline to week one compared to no change on placebo (p-values 0.005, 0.001, 0.032 respectively). Similarly, mean CGI-S scores improved for subjects receiving esketamine at all doses (p-values 0.028, 0.004, 0.049 respectively) compared to no change inplacebo subjects. These data are consistent with previously reported data based on the Montgomery Åsberg Depression Rating Scale (MADRS) and support positive correlation between patient-reported and clinician-reported outcomes.

DISCUSSION: Initial results from this Phase 2a study suggest clinically relevant improvement in depression symptoms in as early as one week when treated with twice-weekly intranasal esketamine as reported by both clinicians and patients. This work will help guide future investigations of esketamine in larger populations to provide better therapeutic options for treatment resistantMDD patients.

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Treatment-Refractory Mania With Psychosis in Post-Transplant Patient on Tacrolimus: A Case Report

Meelie Bordoloi, MD, PGY3[1]; Garima Singh, MD[2]; and Muaid Hilmi Ithman, MD[3]

[1] Psychiatry, University of Missouri-Columbia, Missouri
[2] Assistant Professor of Psychiatry, Thompson center for Autism and Neurodevelopmental disorder, University of Missouri-Columbia
[3] Associate Professor of Psychiatry, Associate Medical Director, MUPC, University of Missouri-Columbia

ABSTRACT: We present a case of a 66 year old Caucasian female with Bipolar type 1 disorder, status post right renal transplant (5/8/14) on maintenance immunosuppression who presented with mania and psychosis. The previous weeks had her being sleep deprived, talkative, making random calls to family members at odd hours, demonstrating pressured speech and also having erotomania regarding Joshua Bell, the violinist. She had recently been switched from Divalproex sodium (on which she had been stable for years) to Quetiapine due to thrombocytopenia attributed to the former. Quetiapine was optimized to 800 mg over two weeks without any improvement. She continued to be severely manic with new delusions of being in a World War II zone and the staff being NAZIs. She continued to be tangential with disorganized behavior and inability to care for self. She was then restarted on Divalproex sodium (for mood) with close monitoring of her counts along with Risperidone (for psychosis). Divalproex sodium was optimized to 1500mg and Risperidone to 6 mg over the next 2 weeks without much improvement. Risperidone was then cross tapered with Olanzepine. We also began to pursue other causes of treatment refractory mania withpsychosis, namely her immunosuppressant medications. She had been placed on maintenance immunosuppression with-tacrolimus (Prograf) 3mg BID, Mycophenolic acid (Myfortic) 360 mg BID and Prednisone 5 mg. Though the most recent Tacrolimus level was within therapeutic range, they were still higher than her baseline levels. Based on few case reports of psychosis associated with Tacrolimus and per discussion with nephrology, we planned cross taper of Tacrolimus and Cyclosporin. Tacrolimus was eventually tapered off and Cyclosporine was maintained at 125 mg qam and 100 mg qpm. Prednisone was maintained at 5 mg daily. Her mania and psychosis improved and she was ultimately discharged on Olanzepine 20mg qhs, Divalproex sodium 1500mg qhs, The problems encountered during this case were plenty due to multiple comorbid conditions including a right adrenal adenoma, hypertension, impaired glucose tolerance, thyroid dysfunction, hyperlipidemia and having bio-prosthetic aortic valve due to Aortic stenosis (2013). In conclusion, psychosis can be precipitated in renal transplant patient with Bipolar disorder I with previously maintained stability on Tacrolimus with other comorbid conditions. So, It would be important to re-evaluate the use of Tacrolimus or the possibility of switching to another immunosuppressive agent with-careful consideration of risks versus benefits. Case

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management should include good coordination of care with Family medicine, Transplant/nephrology team and social services for efficacious and successful management of patient.

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Long-Term Safety of Deutetrabenazine for the Treatment of Tardive Dyskinesia: Results From an Open-Label, Long-Term Study

Karen E. Anderson, MD[1]; Mat D. Davis, PhD[2]; Stewart A. Factor, DO[3]; Robert A. Hauser, MD, MBA[4]; L. Fredrik Jarskog, MD[5]; Joohi Jimenez-Shahed, MD[6]; Rajeev Kumar, MD, FRCPC[7]; Stanislaw Ochudlo, MD, PhD[8]; William G. Ondo, MD[9]; and Hubert H. Fernandez, MD[10]

[1] Georgetown University, Washington, District of Columbia, USA
[2] Teva Pharmaceutical Industries, Frazer, Pennsylvania, USA
[3] Emory University, Atlanta, Georgia, USA
[4] University of South Florida Parkinson's Disease and Movement Disorders Center, Tampa, Florida, USA
[5] University of North Carolina School of Medicine, Chapel Hill, North Carolina, USA
[6] Baylor College of Medicine, Houston, Texas, USA
[7] Rocky Mountain Movement Disorders Center, Englewood, Colorado, USA
[8] University Clinical Center of Silesian Medical University, Katowice, Poland
[9] Methodist Neurological Institute, Houston, Texas, USA
[10] Cleveland Clinic, Cleveland, Ohio, USA

ABSTRACT: Introduction: In the 12-week ARM-TD and AIM-TD studies, deutetrabenazine showed clinically significant improvements in Abnormal Involuntary Movement Scale (AIMS) scores at Week 12 compared with placebo, and was generally well tolerated.

OBJECTIVE: To evaluate the long-term safety/tolerability and efficacy of deutetrabenazine in patients with TD. Week 54 open-labelresults are reported in this interim analysis.

METHODS: Patients with TD who completed ARM-TD or AIM-TD were included in this open-label, single-arm extension study, in which all patients restarted/started deutetrabenazine 12 mg/day, titrating up to a maximum total daily dose of 48 mg/day based on dyskinesia control and tolerability. The study comprised a 6-week titration period and a long-term maintenance phase. Safetymeasures included incidence of adverse events (AEs), serious AEs (SAEs), drug-related AEs, and AEs leading to withdrawal, dose reduction, or dose suspension. This analysis reports results up to Week 54.

RESULTS: 304 patients enrolled in the extension study. There were 215 patient-years of exposure in this analysis, and exposure-adjusted incidence rates (EAIRs) of AEs (incidence/patient-years) were comparable to or lower than those observed with short-term deutetrabenazine treatment and placebo. The frequency of SAEs (EAIR 0.14) was similar to rates observed with short-termplacebo (EAIR 0.33) and deutetrabenazine (EAIR range 0.06–0.33) treatment. AEs leading to study discontinuation (EAIR 0.08), dose reduction (EAIR 0.17), and dose suspension (EAIR 0.09) were uncommon.

CONCLUSIONS: Long-term treatment with deutetrabenazine was generally safe and well tolerated in patients with TD, and did not result in cumulative toxicity.

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Optimizing TMS Treatment for Depression - The 19 Minute Dash™ Protocol

Miriam Mina[1]; David G. Brock, MD[2]; Alvaro Pascual-Leone, MD, PhD[3]; and Mark A. Demitrak, MD[4]

[1] Neuronetics, Inc., Malvern, PA
[2] no affiliation, Ambler, PA
[3] Berenson-Allen Center for Noninvasive Brain Sttimulation, Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, MA
[4] Axovant Sciences, Inc, New York, NY

ABSTRACT: Title: Optimizing TMS treatment for Depression - The 19 Minute Dash™ protocol

OBJECTIVE: NeuroStar transcranial magnetic stimulation (TMS) is an effective treatment for patients with major depressive disorder. Due to the treatment session duration, a reduced treatment time would promote patients' comfort and convenience. Also, shorter treatment sessions of retained efficacy and safety would increase access to treatment. This reduction could be accomplished by decreasing the time between TMS pulse sequences, the intertrain interval (ITI).

METHODS: Meta-analysis of TMS delivered using varying treatment parameters, particularly the ratio of train

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