the proportion of patients who did not meet MetS criteria at DB baseline but developed MetS at endpoint was 9.0% in the adjunctive lurasidone group, and 10.5% in the adjunctive placebo group (LOCF).

CONCLUSION: This post-hoc analysis found that short- and long-term treatment with lurasidone was associated with a relatively low risk for the development of metabolic syndrome in patients with bipolar I disorder. These findings are consistent with similar analyses in patients with schizophrenia.

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161 The NeuroStar Outcomes Registry

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ABSTRACT: Objective: NeuroStar® Advanced Therapy System is an effective acute treatment for patients with major depressive disorder (MDD). To further understand the efficacy of the NeuroStar in a clinical setting, Neuronetics has established the largest patient treatment and outcomes registry for Major Depressive Disorder (MDD) to collect and analyze the efficacy of transcranial magnetic stimulation (TMS) on patients receiving NeuroStar treatment.

METHODS: Individual NeuroStar providers are invited to participate in the registry and over 100 clinical practice sites have agreed to provide their de-identified patient treatment data. An integrated electronic data management system (TrakStar) allows for large-scale data collection to be automated. The data collected for the registry include Demographic Elements (age, gender), Treatment Parameters, and Clinical Ratings. Clinical assessments performed at baseline and the end of acute treatment are the Patient Health Questionnaire 9-item (PHQ-9) and the Clinician Global Impression - Severity of Illness (CGI-S). De-identified patient data is uploaded to a Registry server; an independent statistical service then creates final data reports.

RESULTS: Over 3300 evaluable patients have entered the NeuroStar Outcomes Registry since September 2016. The population is 64% female with a mean patient age of 47.8 (SD±16.9); Mean baseline PHQ-9 is 19.0 (SD ±5.0). Response & remission rate on PHQ-9 is 63% & 33%, and on CGI-S was 76% & 54%, respectively.

CONCLUSIONS: For the over 3300 patients in the Outcomes Registry, approximately 2/3 patients achieve response and 1/3 patients achieve remission with an acute course of NeuroStar TMS. These treatment outcomes are consistent with previous open-label study data (Carpenter et al., 2012) using the NeuroStar system. The NeuroStar Outcomes Registry is ongoing and has surpassed Star*D dataset (Rush et al., 2006) with over 3300 evaluable patients from more than 100 clinical sites in 3 years. Funding Acknowledgements: Funding: Neuronetics, Inc.

162 Post-lithium Delirious Mania in Patients with **Bipolar Disorder**

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ABSTRACT: Delirious mania is a life-threatening condition, presenting with symptoms of acute delirium and psychotic mania as a complication of medical or psychiatric condition. It is not recognized as a diagnosis in DSM-V and is under recognized in clinical practice. It was first described by Calmeil (Calmeil, 1832). In 1849 Luther Bell described 40 cases with an associated 75% mortality rate. More recently, Jacobowski et al (2013) compiled a comprehensive review of clinical characteristics, diagnostic work up, and treatment recommendations for delirious mania. In addition to acute onset, clinical course is frequently worsened by psychosis and catatonia. Delirium leads to disequilibrium of neurotransmitters, particularly depletion of acetylcholine and elevation of dopamine.

Lithium has been used for the treatment of mania for many decades. Suppes et al performed a meta-analysis of 14 studies including 257 patients with Bipolar I disorder and concluded that patients relapsed 28 times more when stopping lithium compared to those who continued this medication. Baldessarini et al (1999) completed analysis of 227 patients with Bipolar I and II disorders, dividing the sample into "abrupt" (1-14 days) and "gradual" (15-30 days) discontinuation groups and concluded that the frequency of relapse following "abrupt" cessation was four times higher compared to following "gradual" cessation. In a study of 450 bipolar patients, Baldessarini et al (2003) reviewed the long-term treatment of lithium as monotherapy (86 % of the study's population) in the context of lithium maintenance population morbidity. Greater pretreatment morbidity lead to larger relative reduction in morbidity as a result of treatment with lithium. A subgroup of bipolar patients with "abrupt"

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discontinuation became refractory when re-challenged with lithium.

Describing three clinical cases of delirious mania following conclusions can be derived:

- Patients with bipolar disorder and comorbid chronic kidney injury currently or formerly receiving long-term therapy with lithium are at increased risk for delirious mania.
- Abrupt lithium discontinuation in patients with bipolar disorder and comorbid chronic medical conditions
 (especially chronic kidney disease) increases risk for
 mania refractory to conventional treatment with
 medications.
- In such patients, definitive treatment is ECT.

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Appreciating Historical Racial and Ethnic Nuance in Developing Novel Approaches to Effective Communication of Mental Illness in the Black Community

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ABSTRACT: There are many barriers to mental health care in the Black Community. These barriers lead to racial disparities in access to treatment and quality of life, along with inappropriate treatment and misdiagnosis in mental and physical health. These disparities directly lead to increased morbidity, mortality and poor mental health in the our communities. Many would question if Black people are not interested in mental health and don't see it as a needed concern. This talk will address that all cultures are not the same and that there is a fundamental need to address communities on their terms and not make them conform into a "majority culture" approach and perception of mental health care, but rather focus on the individual patient and community needs for mental health care. Often psychiatrists and other mental health professionals are trained in a very academic scientific approach to identification and treatment of mental illness. Too often this model does not fit the needs of all patients due to it not taking into account ethnic differences in communication of mental health and desired outcomes of the patient. This often leads to a lack of understanding on with both sides, the mental health professional and the patient. Too often a patient may see the physician, be given a diagnosis, starts taking a prescription, but then not be able to explain what is their diagnosis, the name of the medication, what it is for, nor what is the medication supposed to do for them. This could lead to unexpected poor outcomes due to the lack of effective communication. This talk will attempt to explain the barriers of communication to the Black community while appreciating and supporting cultural nuance and effective communication. This is needed to help bring mental health to the community in a digestible way and to meet the communities needs on their level. To do this, psychiatry needs to shift it's focus to understanding cultural characteristics, such as how Black patients may have different cultural needs and may benefit from a unique, customized approach to their mental health. There is a need for psychiatry to take into consideration the spiritual aspects of patients and how many focus not only on needing to improve themselves, but also on how their mental health and behavior are impacting their family and the community as a whole. The traditional model of interview, diagnosis with medication, and follow up for medication adjustment is not fitting all communities leading to the detriment of their mental health.

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Pooled Analyses of Patient-Reported Sleep Onset and Maintenance from Two Phase 3 Studies of Lemborexant

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ABSTRACT: Study Objective(s): The dual orexin receptor antagonist, lemborexant (LEM), is being investigated for the treatment of insomnia disorder. Drugs targeting the orexin system, like LEM, may decrease wakefulness and promote sleep with fewer potential adverse effects (AEs) than some currently available pharmacological insomnia therapies. LEM has been studied in 2 pivotal phase 3 trials for insomnia disorder, SUNRISE-1 (NCT02783729; E2006-G000-304) and SUNRISE-2 (NCT02952820; E2006-G000-303). Analyses presented here are derived from patient-reported (subjective) efficacy data pooled from SUNRISE-1 and SUNRISE-2 during 1-month of treatment in adult and elderly (age ≥65y) subjects with DSM-5 insomnia disorder.

METHOD: SUNRISE-1 was a 1-month, double-blind, randomized, placebo (PBO)- and active-controlled (zolpidem tartrate extended-release 6.25mg [ZOL; not reported), parallel-group study in 1006 subjects (age ≥55y). SUNRISE-2 was a 12-month (6-month PBO-controlled, 6-month active treatment), double-blind study in 949 subjects (age ≥18y). In both studies, subjects were randomized to PBO,