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,

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LEM5, or LEM10 (SUNRISE-1 subjects could also be randomized to ZOL; not included in pooled analysis) following a 2-week PBO run-in. Changes from baseline (BL) in subjective sleep onset latency (sSOL), subjective sleep efficiency (sSE), and subjective wake after sleep onset (sWASO) were analyzed using mixed effect model repeated measurement analysis. Sleep onset and sleep maintenance responders were analyzed via Cochran–Mantel–Haenszel test stratified by study, region and age group.

RESULTS: The pooled analysis set comprised 1693 subjects (PBO, n=527; LEM5, n=582; LEM10, n=584). Reductions from BL in sSOL were significantly greater for LEM5 and LEM10 vs PBO during the first 7 days of treatment and at the end of Month 1 (all comparisons P<0.0001). Both doses of LEM significantly increased sSE from BL (P<0.001 both time points) more than PBO and reduced sWASO from BL (P<0.0001 first 7 days [both doses]; P<0.05 [LEM5] and P<0.001 [LEM10] at Month 1) more than PBO. After the first 7 days and at the end of Month 1, the proportion of sSOL responders (≤20 min if BL >30 min) was statistically significantly larger for LEM5 and LEM10 vs PBO (first 7 days: both P<0.0001; last 7 days of Month 1: both P<0.001) and the proportion of sWASO responders (≤60 minutes and a reduction from BL by >10 min, if BL >60 min) was statistically significantly larger for LEM5 and LEM10 vs PBO (first 7 days: both P<0.01; last 7 days of Month 1: both P<0.05). LEM was well tolerated. Most AEs were mild to moderate in severity, and rates of severe or serious AEs were low.

CONCLUSIONS: LEM improved sleep onset and sleep maintenance in adult and elderly subjects with insomnia disorder, and was well tolerated. Average values on sleep maintenance endpoints showed that subjects treated with LEM obtained >1 hour of additional sleep per night vs subjects who received PBO.

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Impact of Lemborexant on Insomnia Disease Severity and Fatigue: Results from the 6-Month Placebo-Controlled Period of the Phase 3 SUNRISE-2 Study

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ABSTRACT: Study Objective(s): This study examined the effects of lemborexant (LEM) compared with placebo (PBO) on subject-reported insomnia disease severity, assessed by the Insomnia Severity Index (ISI), and fatigue, assessed by the Fatigue Severity Score (FSS), from the 6-month PBO-controlled period of SUNRISE-2.

METHOD: SUNRISE-2 (NCT02952820; E2006-G000-303) was a 12-month randomized, double-blind, PBO-controlled (first 6-months) Phase 3 study. After an ~2-week PBO run-in, subjects were randomized to PBO, LEM 5mg (LEM5) or LEM 10mg (LEM10) for 6 months. The ISI and the FSS were administered at baseline [BL] and at the end of Months 1, 3, and 6. The ISI daytime functioning score (DFS), based on the ISI items that assess the impact of insomnia symptoms specific to daily functioning (items 4-7), was also evaluated. Mean changes from BL in ISI total score (ISI TS), ISI DFS, and FSS total score (FSS TS) were analyzed using a mixed-effect model repeated measurement analysis, adjusted for relevant factors and BL score (ISI TS, ISI DFS, or FSS TS) as a covariate.

RESULTS: 949 subjects (PBO, n=318; LEM5, n=316; LEM10, n=315) were included in the full analysis set. Median age was 55y (range 18-88y). Mean ISI TS at BL for PBO, LEM5, and LEM10 was 19.0, 19.6 and 19.1, respectively. While mean ISI TS decreased (improved) from BL for all groups, decreases were significantly larger for both LEM5 and LEM10 vs PBO at Month 1 (least squares mean treatment difference [LSM TD]: LEM5, −1.5 [P=0.001]; LEM10, −1.9 [P<0.0001]), Month 3 (LSM TD: LEM5, −2.0; LEM10, −2.6 [both P<0.0001]), and Month 6 (LSM TD: LEM5, −2.1; LEM10, −2.4 [both P<0.0001]). Decreases from BL in mean ISI DFS were also significantly larger for LEM5 and LEM10 vs PBO at Month 1 (LSM TD: LEM5, −0.7 [P=0.014]; LEM10, −0.9 [P=0.001]), Month 3 (LSM TD: LEM5, −1.2 [P=0.0001]; LEM10, −1.4 [P<0.0001]), and Month 6 (LSM TD: LEM5, −1.3; LEM10, −1.3 [both P<0.0001]).
Mean FSS TS at BL was 35.2, 37.4, and 36.0 for PBO, LEM5, and LEM10, respectively. Mean FSS TS decreased (improved) from BL in all groups at the end of Month 1 (decreases were larger and significant for LEM10 vs PBO [LSM TD: –2.0 (P=0.026)]), and Month 3 (decreases were larger and significant for LEM5 [LSM TD: –2.2 (P=0.021)] and LEM10 [LSM TD: –3.0; (P=0.001)] vs PBO). At Month 6, mean FSS TS remained improved from BL in all treatment groups (PBO, –6.3; LEM5, –10.1; and LEM10, –8.9). These decreases were larger and significant for LEM5 (LSM TD: –2.5 [P=0.013]) and LEM10 (LSM TD: –2.6 [P=0.013]) vs PBO. LEM was well tolerated with most adverse events mild to moderate in severity.

CONCLUSIONS: In SUNRISE-2, LEM5 and LEM10 significantly reduced subject-reported disease severity and

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