(REM) sleep. Lemborexant (LEM), a dual-orexin-receptor-antagonist approved to treat adults with insomnia, increases total sleep time (TST) and REM sleep, and demonstrated respiratory safety in subjects with mild through severe OSA. Sleep architecture was thus analyzed after LEM treatment in those subjects. Methods: Studies E2006-A001-102 and E2006-A001-113 enrolled adults with mild (apnea-hypopnea index [AHI] ≥5 – <15) or moderate (AHI ≥15 – <30)/severe (AHI ≥30) OSA without insomnia. Subjects received LEM 10mg (LEM10) or placebo (PBO) in 2 treatment periods, Days 1 (D1) and 8 (D8), separated by ≥14 days. Least-squares-mean (minutes) for each sleep stage was compared. Treatment-emergent adverse events (TEAEs) were recorded. Results: Thirty-nine subjects with mild and 33 with moderate/severe OSA were randomized. On both days, TST was significantly higher in the LEM period for these subjects. Total non-REM on D1 in subjects with mild OSA and on both days in subjects with moderate/severe OSA were higher with LEM than PBO; REM also significantly increased in subjects with mild and moderate/severe OSA. Most TEAEs were mild. Conclusions: In OSA subjects without insomnia, LEM was associated with higher TST, non-REM, and REM versus PBO.

P.051

Effect of lemborexant on cognition in patients with comorbid insomnia disorder and mild obstructive sleep apnea

M Moline (Nutley) JY Cheng (Nutley) D Kumar (Nutley) B Ramos (Mississauga) AD Lowe (Toronto)*

doi: 10.1017/cjn.2023.155

Background: Some sleep-promoting medications are associated with cognitive impairment, making treatment of comorbid obstructive-sleep-apnea (OSA) and insomnia (COMISA) challenging. Lemborexant is a dual-orexin-receptor-antagonist approved for insomnia treatment. This post-hoc analysis evaluated cognition in the subgroup of subjects with mild-OSA (apnea-hypopnea-index ≥5–<15 events/h-of-sleep). Methods: Study E2006-G000-304 was a 1-month, randomized, double-blind, placebo (PBO)- and active-comparator (zolpidem-ER 6.25mg [ZOL])-controlled study of lemborexant 5/10mg (LEM5/LEM10). Subjects ≥55y with insomnia disorder/sleep maintenance problems were enrolled (N=1006). A cognitive-performance assessment battery (CPAB) was performed at morning waketime of Days(D)2/3 and D30/31. Change-from-baseline (CFB) for mean power-of-attention (PoA), continuity-of-attention (CoA), quality-of-memory (QoM), and speed-of-memory-retrieval (SoMR) for CPAB tasks was analyzed. Results: The mild-OSA subgroup comprised 410 (40.8%) subjects. On D2/3 and D30/31, CFB for PoA, CoA, QoM, and SoMR for LEM5/LEM10 were not significantly different than PBO. On D2/3, PoA and QoM were significantly worse with ZOL vs PBO; QoM was significantly better with LEM5/LEM10 vs ZOL. On D30/31, SoMR was significantly worse with ZOL vs PBO and significantly better with LEM5/LEM10 vs ZOL. LEM safety in the subgroup was consistent with the overall study population. Conclusions: Memory and attention domains in subjects with COMISA characterized by mild-OSA were not impacted by LEM, unlike ZOL.

Support: Eisai Inc.

P.052

Trazodone for treating insomnia: abuse and safety risks

M Moline (Nutley) T Juday (Nutley) JY Cheng (Nutley) J Henningfield (Bethesda) A Buchhalter (Bethesda) MA Sembower (Bethesda) S Pype (Bethesda) EM Wickwire (Baltimore) RM Procyshyn (Vancouver)*

doi: 10.1017/cjn.2023.156

Background: Although unapproved by the FDA for treating insomnia, trazodone is commonly prescribed in the US partly due to lack of scheduling, hence it's perceived as safer than z-drugs and benzodiazepines. This study investigated trazodone abuse/dependence potential and safety risks. Methods: Cases involving trazodone or benzodiazepines (temazepam, triazolam, estazolam) frequently prescribed for insomnia were identified from the FDA Adverse Events Reporting System (FAERS), National Forensic Laboratory Information System (NFLIS) for confiscation data, and the American Association of Poison Control Centers'-National Poison Data System (AAPCC-NPDS). Drug-related falls risk was assessed from claims databases. Results: FAERS included 11,228 trazodone and 5120 benzodiazepine reports. Of these, drug-abuse and drug-dependence cases with trazodone were lower than benzodiazepines (drug-abuse: 6.4%/12.6%; drug-dependence: 1.1%/3.6%). Serious cases (81.8%/83.9%) and deaths (35.4%/36.0%), were similar between trazodone and benzodiazepines. NFLIS reported 612/1,575,874 (0.04%) drug-seizure cases that included trazodone. AAPCC-NPDS reported 22,225/1,446,011 (1.54%) total case mentions of trazodone/all pharmaceuticals and 8445 trazodone-related single-exposure cases. Falls risk (1year-period) in Medicare beneficiaries ≥65y and commercially-insured enrollees ≥18y was reported for trazodone and benzodiazepines: Medicare, 9.5%/11.3%; Commercially-insured: 4.6%/3.7%. Conclusions: Trazodone has abuse/dependence potential and important safety risks. Given limited data from well-controlled studies and off-label use, re-evaluation of trazodone prescribing rates in patients with insomnia is warranted.

P.053

Efficacy of lemborexant in adults with insomnia is supported by improvements in both objective and subjective measures

M Moline (Nutley) CM Morin (Quebec) D Kumar (Nutley) C Lundwall (Nutley) K Pinner (Hatfield) B Ramos (Mississauga) A Desautels (Montreal)*

doi: 10.1017/cjn.2023.157

Background: Improvements in sleep-onset, maintenance, and daytime functioning, are all important outcomes for the treatment of insomnia. These improvements are usually assessed by objective or patient-reported (subjective) measures or both. Some sleep-promoting drugs do not report consistently aligned subjective and objective outcomes. Therefore, we examined concordance in change from baseline (CFB) in sleep parameters (objective/subjective measures) and daytime functioning (subjective measures) in the clinical program of lemborexant (LEM), a dual-orexin receptor antagonist. Methods: Study E2006-G000-304 (NCT02783729),