(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

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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

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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

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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),

a 1-month, placebo (PBO)- and active-controlled (zolpidem; not discussed here) study, and Study E2006-G000-303 (NCT02952820), a 12-month, randomized, PBO-controlled study (first 6-months), evaluated the efficacy/safety of LEM 5mg (LEM5) and LEM 10mg (LEM10) in subjects with insomnia disorder. The primary/secondary endpoints in both studies included multiple objective/subjective sleep parameters and patient-reported measures, which were assessed for concordance. Results: In both studies, statistically significant improvements with LEM5/LEM10 were reported in multiple objective and patient-reported measures versus PBO, showing a concordance of results, with observed improvements continuing through 12 months. LEM was well tolerated; most treatment-emergent adverse events were mild/moderate. Conclusions: When deciding which sleep agent to prescribe, it is important that improvement can be demonstrated in both objective and patient-reported measures. LEM treatment showed concordance among observed measures.

P.054

Older subjects with insomnia disorder and comorbid pain at baseline: response to Lemborexant

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Background: There is a well-established reciprocal relationship between pain and poor sleep. Therefore, we evaluated whether an approved sleep-promoting drug, lemborexant (LEM), could improve sleep in older adults who reported both insomnia and pain. Methods: Study E2006-G000-304 (NCT02783729) was a 1-month, placebo (PBO)- and active-controlled study in subjects (age ≥55y) with insomnia disorder. Those reporting some/severe pain on the pain/discomfort dimension of the EQ-5D-3L at baseline were included. Subjects were randomized to placebo (PBO), LEM 5mg (LEM5), 10mg (LEM10) or zolpidem (not reported here). Changes from baseline (CFB) in objective sleep parameters latency-to-persistent sleep (LPS) and total-sleep-time (TST) were analyzed in paired polysomnograms. Results: 183/743 (24.6%) subjects in the PBO (n=55/208[26.4%]), LEM5 (n=78/266[29.3%]) and LEM10 (n=50/269[18.6%]) treatment groups reported some/extreme pain at baseline, with median LPS (minutes): 31.0, 29.4, 42.1, respectively. Respective median CFB for LPS at the beginning (Nights[NT]1/2: +2.5, –8.4, –15.8; P<0.005) was significantly larger/decreased for LEM5/LEM10 versus PBO and LEM5 at treatment end (NT29/30: –7.1, –9.9, –9.0; P=0.031). Mean baseline TST (minutes) was 335.3 (PBO), 336.3 (LEM5), 324.3 (LEM10), and mean CFB was significantly larger/increased (P<0.001) for LEM5/LEM10 versus PBO at NT1/2 and NT29/30. Conclusions: Results suggest LEM may effectively treat insomnia in older adults with comorbid pain.

Support: Eisai Inc.

P.055

Does age matter in the CaRMS neurology match?

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Background: The Canadian Resident Matching Services (CaRMS) collects comprehensive data on residency applicants. However, match outcomes by age were not reported. It was unclear whether older applicants found it more difficult to match to the specialties of their choice, i.e. does age influence match? We ask in particular, does age affect the neurology match? Methods: In response to written request, CaRMS provided pre-pandemic age data for 2015-2019 inclusive, divided into group 1 (30 or younger) and group 2 (31-40 inclusive). Results: In 2019, 39 of the 69 group 1 and 6 of the 23 group 2 neurology applicants were matched into neurology (odds ratio (OR)=2.2|p=0.01). In contrast, urology (OR=6|p=0.001) had the worst odds and family medicine (OR=1.2|p=0.002) had the best odds for older applicants in 2019. Average OR (2015-2019) was 1.6 for neurology, 3.1 for urology, 1.3 for family medicine, and between 1.3 and 3.1 for nearly all other specialties. Conclusions: Older neurology applicants were less likely to match than younger peers while match probability was statistically significantly lower in nearly all specialties for older applicants.

P.056

Dual-energy CT for differentiating intracerebral hemorrhage from Contrast Extravasation after Acute Ischemic Stroke Intervention (DECT-ICH)

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Background: Thrombolysis (tPA) and endovascular thrombectomy (EVT) are interventions for acute ischemic stroke (AIS) that can be accompanied by intracerebral hemorrhage (ICH), which can alter the patient's management, or contrast extravasation (CE), which is relatively benign. Previous retrospective studies have shown that dual-energy CT (DECT) is significantly more accurate for differentiating ICH from CE compared to conventional, single-energy CT (SECT). We are performing a prospective study to investigate this question. Methods: Our primary outcome is the sensitivity and specificity of DECT in differentiating ICH from CE. In AIS patients who receive intervention, we will be performing a DECT scan at the same time as the standard-of-care SECT scan at 24 hours post-intervention. In patients who have a hyperdensity on CT, a repeat scan will be done at 72-hours, which will be used as the gold-standard to determine if the hyperdensity was ICH or CE. Results: We expect that DECT will be significantly more sensitive and specific for differentiating ICH from CE compared to SECT.