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Introduction: Among elderly persons (age ≥65 years), insomnia is a prevalent sleep disorder. Lemborexant (LEM) is a dual orexin receptor antagonist approved in multiple countries, including the United States, Japan, Canada, Hong Kong, Australia, and India, for the treatment of insomnia in adults (age ≥18 years). Clinical trials for insomnia therapies include data from daily sleep diaries to assess the magnitude of change quantitatively in subjective sleep outcomes, including sleep onset and maintenance. Additionally, there are instruments that assess patient estimates of time to sleep onset and duration of nighttime awakenings. Assessment of symptom improvement provides critical information on treatment effectiveness. The demonstration of improvement in sleep from the patient's perspective is important in the assessment of the effectiveness of an insomnia therapy, as insomnia is a symptom-based disorder. The Patient Global Impression−Insomnia version (PGI-I) is a self-report instrument used to evaluate a patient's perception (qualitative) of the effects of their insomnia medication on their sleep relative to their sleep before starting their treatment. The PGI-I includes 3 items related to medication effects (helped/worsened sleep; decreased/increased time to fall asleep; and increased/decreased total sleep; choices for patient responses include: 1=positive, 2=neutral, 3=negative). The PGI-I also includes 1 item related to perceived appropriateness of study medication strength with a different set of possible responses (choices for patient responses include: 1=too strong, 2=just right, 3=too weak). In Study E2006-G000-303 (Study 303; SUNRISE-2; NCT02952820), significantly greater percentages of subjects in the age ≥65 years subgroup reported a positive impact of LEM versus placebo (PBO) at 1, 3 and 6 months for each of the PGI-I items related to medication effects. The majority of subjects also reported medication strength as "just right" at 1, 3 and 6 months. PGI-I results at 9 and 12 months for subjects age ≥65 years are presented here for subjects that received continuous treatment with LEM for up to 12 months in Study 303.

Methods: Study 303 was a Phase 3, 12-month, double-blind, global study in adults age ≥18 years with insomnia disorder that included a 6-month PBO-controlled period (Treatment Period 1) followed by a 6-month active-only (Treatment Period 2) period. Subjects received PBO, LEM 5mg (LEM5) or LEM 10mg (LEM10) for the first 6 months. For Treatment Period 2, PBO-treated subjects were rerandomized to LEM (not reported here), while LEM-treated subjects continued their original dose. Titration to higher or lower doses was not permitted. The PGI-I was administered at Months 1, 3, 6, 9, and 12. Results for the PGI-I were analyzed by age (age ≥65 years).

Results: The Full Analysis Set comprised 949 subjects, of which 262 (27.6%;[PBO, n=89; LEM5, n=87; LEM10, n=86]) were age ≥65y. At 9 and 12 months, the majority of elderly LEM5-treated (total treated up to 9 months, n=68; total treated up to 12 months, n=61) and LEM10-treated (total treated up to 9 months, n=61; total treated up to 12 months, n=56) subjects reported that their study medication "helped" sleep at night (9 months: LEM5=51 [75.0%], LEM10=45 [73.8%]; 12 months: LEM5=47 [77.0%], LEM10=42 [75.0%]), reduced time to fall asleep (9 months: LEM5=59 [86.8%], LEM10=47 [77.0%]; 12 months: LEM5=53 [86.9%], LEM10=44 [78.6%]), and increased total sleep time (9 months: LEM5=43 [63.2%], LEM10=45 [73.8%]; 12 months: LEM5=38 [62.3%], LEM10=33 [58.9%]). Also, at both 9 and 12 months, the majority of subjects in the LEM5 and LEM10 groups responded that their medication strength was "just right" (9 months: LEM5=46 [67.6%], LEM10=37 [60.7%]; 12 months: LEM5=43 [70.5%], LEM10=37 [66.1%]). LEM was well tolerated. Most adverse events were mild or moderate.

Conclusions: The majority of elderly subjects receiving LEM5 or LEM10 for up to 12 months reported a positive medication effect and perceived their medication strength as "just right" at both 9 and 12 months. These results demonstrate that the similar positive perceptions of the effects of LEM achieved during Treatment Period 1 in the elderly subgroup were sustained through Treatment Period 2.

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SUBJECTIVE RATINGS OF MEDICATION STRENGTH OVER 6 MONTHS IN ELDERLY SUBJECTS WITH MODERATE OR SEVERE INSOMNIA TREATED WITH LEMBOREXANT

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