

[Notes to editors]

1. About lemborexant

Lemborexant (development code: E2006), a dual orexin receptor antagonist, is an in-house discovered and developed small molecule compound by Eisai which inhibits orexin by binding competitively to two subtypes of orexin receptors (orexin receptor 1 and 2). In individuals with insomnia disorder, it is possible that the orexin system which regulates sleep and wakefulness is not functioning normally. During normal periods of sleep, orexin system activity is suppressed, suggesting it is possible to purposefully facilitate the initiation and maintenance of sleep by interfering with orexin neurotransmission with lemborexant.

A Phase III study of lemborexant in insomnia is underway, and in addition, Eisai has announced the initiation of Phase II clinical studies of lemborexant in patients with irregular sleep-wake rhythm disorder (ISWRD) and mild to moderate Alzheimer's disease.

2. About ISWRD (Irregular Sleep-Wake Rhythm Disorder)

ISWRD is a type of circadian rhythm sleep disorder where the pattern of sleep and wakefulness that repeats itself over a 24 hour period in healthy individuals is broken down, and sleeping and waking occur instead at various times during the day and night. This is often observed in patients with dementia. Although referred to in this press release as ISWRD, the condition is also known as Circadian Rhythm Sleep Disorder (Irregular Sleep Wake Type).

3. About Study 202

Study 202 is a multicenter, randomized, double-blind, placebo-controlled, parallel-group Phase II clinical study of the efficacy and safety of lemborexant in subjects with ISWRD and mild to moderate Alzheimer's disease dementia (AD) conducted in the United States and Japan. Patients with ISWRD associated with AD will be administered 2.5 mg, 5 mg, 10 mg or 15 mg of lemborexant or placebo for 4 weeks to determine whether at least one dose of lemborexant is superior to placebo on the change from baseline of mean sleep efficiency (ratio of time spent asleep to the total amount of time spent in bed) and wake efficiency (ratio of time spent awake to the total amount of time not asleep at night) during the last week of 4 weeks of treatment, as measured by actigraphy.

4. About Study 304

Study 304 is a multicenter, randomized, double-