Phase 2 Trial Begins for Lemborexant for Irregular Sleep–Wake Rhythm Disorder

Eisai, Inc., and Purdue Pharma announced the initiation of a multi-center, randomized Phase 2 clinical study (Study 202) to evaluate Eisai’s oral dual orexin receptor antagonist lemborexant in patients with mild to moderate Alzheimer’s disease (AD) who experience irregular sleep–wake rhythm disorder (ISWRD).

Study 202 will evaluate the efficacy and safety of lemborexant in 125 patients ages 65 to 90 with ISWRD and mild to moderate AD. Patients will be randomized to receive 2.5, 5, 10, or 15 mg of lemborexant or placebo orally once daily for 4 weeks. Over the 4 weeks of treatment with lemborexant compared to placebo, the primary endpoint will be the dose response of the change from baseline in actigraphy-based sleep and wake efficiency during the last 7 nights of treatment. These changes will be measured using actigraphy, a non-invasive device worn on the wrist that is used to assess sleep–wake patterns continuously for many days.


U.S. Food and Drug Administration Grants Fast Track Designation for New BACE Inhibitor for Alzheimer’s Disease

Eisai, Inc., announced that it has received U.S. Food and Drug Administration Fast Track designation for the development of E2609, a beta-secretase cleaving enzyme (BACE) inhibitor currently being evaluated in Phase 3 clinical trials for early Alzheimer’s disease (AD).

E2609 is an investigational next-generation oral candidate for the treatment of AD that inhibits BACE, a key enzyme in the production of amyloid beta peptides. By inhibiting BACE, E2609 may decrease the formation of toxic amyloid beta peptide aggregates and amyloid plaques in the brain, thereby potentially slowing disease progression. The first Phase 3 study for E2609 in the clinical trial program called MISSIONAD began in October 2016 with 1,330 patients with biomarkers confirmed for early AD.