U.S. Food and Drug Administration Approves New Drug for Migraine

The U.S. Food and Drug Administration (FDA) approved Aimovig™ for preventive treatment of migraine in adults. The treatment is given by once-monthly self-injections. Aimovig is the first FDA-approved preventive migraine treatment in a new class of drugs that work by blocking the activity of calcitonin gene-related peptide, a molecule that is involved in migraine attacks.

The effectiveness of Aimovig for preventive treatment of migraine was evaluated in three clinical trials. The first study included 955 participants with a history of episodic migraine and compared Aimovig to placebo. Over the course of 6 months, Aimovig-treated patients experienced, on average, one to two fewer monthly migraine days than those on placebo. The second study included 577 patients with a history of chronic migraine and compared Aimovig to placebo. Over the course of 3 months, patients treated with Aimovig experienced, on average, 2.5 fewer monthly migraine days than those receiving placebo.

Phase 3 Clinical Trials of Lanabecestat Discontinued for Futility

Eli Lilly and Company and AstraZeneca are discontinuing the global Phase 3 clinical trials of lanabecestat, an oral beta secretase cleaving enzyme inhibitor, for the treatment of Alzheimer’s disease (AD). The decision is based on recommendations by an independent data monitoring committee that concluded that the AMARANTH trial, in early AD, and the DAYBREAK-ALZ trial, in mild AD, were not likely to meet their primary endpoints upon completion and therefore should be stopped for futility.

The AMARANTH trial randomized patients with early AD to receive lanabecestat, 20 mg or 50 mg, or placebo orally once per day for 104 weeks. The primary endpoint of the trial was change from baseline on the 13-item Alzheimer’s Disease Assessment Scale-Cognitive Subscale (ADAS–Cog13).

The DAYBREAK-ALZ trial randomized patients with mild AD to receive lanabecestat, 20 mg or 50 mg, or placebo orally once per day for up to 156 weeks. The primary endpoint of the trial was change from baseline on ADAS–Cog13.


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