BioSpectrum the business of Bio & Health Sciences

Teva Provides Update on Clinical Trial of Fremanezumab

18 June 2018 | News

Fremanezumab is currently under review by the U.S. Food and Drug Administration (FDA), with an action date of September 16, 2018, and by the European Medicines Agency (EMA), as a quarterly or monthly injection for the preventive treatment of migraine in adults.

Teva Pharmaceutical Industries Ltd. announced a change in the clinical development program of fremanezumab in chronic cluster headache.

The ENFORCE Phase III clinical development program includes a chronic cluster headache study, an episodic cluster headache study, and a long-term safety study.

A pre-specified futility analysis of the chronic cluster headache study revealed that the primary endpoint of mean change from baseline in the monthly average number of cluster headache attacks during the 12-week treatment period is unlikely to be met. There were no safety concerns observed with fremanezumab treatment in the trial.

Based on the study meeting the futility criteria, the Company will discontinue the trial for chronic cluster headache. Chronic Cluster Headache patients who participate in the long-term safety study, will discontinue their participation in the long-term safety study as well. The episodic cluster headache study is not affected and continues as planned.

“While we are disappointed with this outcome, we remain optimistic that fremanezumab could have clinical benefits in additional conditions, beyond migraine, where calcitonin gene-related peptide (CGRP) plays a contributory role in their pathophysiology.

We would like to thank the patients and investigators for their participation in the Chronic Cluster Clinical Trial," said Tushar Shah, M.D., Senior Vice President, Head of Global Specialty Clinical Development at Teva.

Fremanezumab is currently under review by the U.S. Food and Drug Administration (FDA), with an action date of September 16, 2018, and by the European Medicines Agency (EMA), as a quarterly or monthly injection for the preventive treatment of migraine in adults.