BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Lilly's experience and competitive advantage will establish Emgality in the migraine market: Global Data

June 6, 2019 | News

For episodic cluster headache, the recommended dosage of Emgality is 300 mg (administered as three consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.



Eli Lilly and Company recently announced that the U.S. Food and Drug Administration has approved Emgality (galcanezumab-gnlm) injection (300 mg) for the treatment of episodic cluster headache in adults. Emgality is an innovative therapeutic approach for this neurologic disease and the first and only calcitonin gene-related peptide (CGRP) antibody approved by the FDA for two distinct headache disorders. After training by a healthcare professional, patients can administer Emgality at home through subcutaneous injections at the onset of a cluster headache period, and then monthly until the end of a cluster period. Emgality was first approved by the FDA in September 2018 for the preventive treatment of migraine in adults and is contraindicated in patients with serious hypersensitivity to galcanezumab-gnlm or to any of the excipients.

Following the approval of Emgality, Alessio Brunello, Senior Pharma Analyst at GlobalData, a leading data and analytics company, offers his view on the first drug to gain FDA US approval for decreasing the frequency of episodic cluster headache attacks:

“As Eli Lilly is the only company to have begun trials in Japan with the drug, Emgality is expected to be a first-in-class therapy in this country, which is likely to give it slightly higher sales than Teva’s Ajovy. GlobalData anticipates that Emgality will generate sales of $1.02bn by 2026, making it the second highest seller in the migraine market. GlobalData also anticipates that Emgality will generate sales of $766M by 2026 in the US alone.

"Episodic cluster headache can be devastating. The approval of Emgality for the treatment of episodic cluster headache is an important milestone as it provides a new treatment option, which has been long-awaited by those impacted by this disease," said Christi Shaw, president, Lilly Bio-Medicines in a release.

"As someone impacted by cluster headache and an advocate for others living with this disease, I know firsthand the desperation that we have felt for additional treatment options that can reduce the frequency of these attacks that have such a debilitating impact on our lives," said Bob Wold, founder, Clusterbusters, Inc."The approval of Emgality for the treatment of episodic cluster headache is a cause for celebration and hope. On behalf of this community, we thank the FDA, Lilly, the researchers and the patients who helped to usher forward this innovative treatment."

The efficacy of Emgality was evaluated for the treatment of episodic cluster headache in a randomized, 8-week, double-blind, placebo-controlled study. In the study, 106 patients were randomized 1:1 to receive once-monthly injections of Emgality 300 mg (N=49) or placebo (N=57), with a baseline number of weekly cluster headache attacks of 17.8 for Emgality and 17.3 for placebo. Patients on Emgality experienced an average of 8.7 fewer weekly cluster headache attacks over Weeks 1 to 3 vs. 5.2 fewer weekly attacks for patients on placebo (p=0.036). With Emgality, 71.4% of patients had their weekly cluster headache attacks cut in half or more from baseline at Week 3 vs. 52.6% of patients with placebo (p=0.046).

Overall, the safety profile observed in patients with episodic cluster headache treated with Emgality 300 mg monthly is consistent with the safety profile in patients with migraine treated with Emgality 120 mg monthly. Two Emgality-treated patients discontinued double-blind treatment during the episodic cluster headache study because of adverse events.

"For years, there have been few therapeutic options to offer patients for the treatment of episodic cluster headache. With today's approval, physicians are now armed with an FDA-approved medication that has the potential to help patients living with this condition by reducing the frequency of cluster attacks," said David Kudrow, M.D., director, California Medical Clinic for Headache.

For episodic cluster headache, the recommended dosage of Emgality is 300 mg (administered as three consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then monthly until the end of the cluster period.

Emgality will be available to patients for pickup at retail pharmacies. The U.S. list price of Emgality for the treatment of episodic cluster headache is the same per milligram as the migraine indication.