

FDA approves of new treatment to help reduce the frequency of episodic cluster headaches

On June 4th, 2019, the U.S. Food and Drug Administration, approved Emgality (galcanezumab-gnlm) for the treatment of episodic cluster headache in adults.¹ Previously, Emgality was only approved as a preventative treatment for migraines. The recommended dose of Emgality is 300 mg subcutaneously (consecutive subcutaneous injections of 100 mg each) at the onset of the cluster period, and then once monthly until the end of the cluster period.² This differs from the dosing of migraine prophylaxis which is a 240 mg loading dose (administered as two consecutive injections of 120 mg each), followed by monthly doses of 120 mg.

Cluster headaches, which are the most painful types of headaches, occur in cyclical patterns or cluster periods often during the same time of the day.³ A headache can last from 15 minutes to 3 hours and usually occurs every day, sometimes multiple times a day. These headaches are characterized by severe pain on one side of the head (orbital, supraorbital, and/or temporal regions). Symptoms that occur with these headaches are: bloodshot eyes, flushing, restlessness, excessive tearing of the eyes, drooping of the eyelids, runny nose and/or congestion and facial swelling. The headaches can last for approximately one week to a year, followed by a period where the headaches stop (remission period), which can last for as long as 12 months before another cluster headache develops

A three-week clinical trial was conducted in 106 patients to demonstrate the effectiveness of Emgality as a treatment for episodic headaches compared to placebo.¹ The trial measured the average number of cluster headaches patients experienced every week and compared the average changes from baseline in the Emgality and placebo groups. Patients taking Emgality experienced 8.7 fewer weekly cluster headaches from baseline versus placebo which experienced 5.2 fewer weekly attacks from baseline.

Hypersensitivity reactions can occur when using Emgality and the medication should be discontinued if that occurs.¹ In the clinical trial the most common side effect reported was injection site reactions.

References:

1. FDA approves first treatment for episodic cluster headache that reduces the frequency of attacks. FDA. Available at: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-episodic-cluster-headache-reduces-frequency-attacks>. Accessed June 10, 2019.
2. Emgality [package insert]. Indianapolis, IN: Eli Lilly and Company; 2019.
3. Mayo Clinic Staff. Cluster Headache [updated June 4th, 2019]. Mayo Foundation for Medical Education and Research. Available at: <https://www.mayoclinic.org/diseases-conditions/cluster-headache/symptoms-causes/syc-20352080>. Accessed June 10, 2019.

Lucy Luo, PharmD. Candidate