NEWS

EMGALITY APPROVAL BRINGS NEW HOPE FOR PREVENTING MIGRAINES

Posted by Angie Glaser | Nov 20, 2018 | 37

EMGALITY IS APPROVED IN US, EU FOR MIGRAINE PREVENTION

A new class of migraine meds is bringing hope to the migraine and headache community. Eli Lilly just announced that Emgality (galcanezumab) has been approved by the European Commission for the prevention of Migraine.

Eli Lilly also announced this week that the FDA granted a Breakthrough Therapy Designation for Emgality for its ability to prevent cluster headaches. The company is expected to file with the FDA by the end of the year for cluster headache prevention (1).

Emgality was approved by the U.S. FDA for Migraine prevention last September. Emgality targets the peptide CGRP, which is actively involved in Migraine pathophysiology. Emgality is the third anti-CGRP treatments to gain approval this year for the prevention of Migraine in adults.

Aimovig, manufactured by Amgen and Novartis, was approved in May. Teva's formulation, Ajovy, was approved in September. A fourth and final anti-CGRP preventative, eptinezumab, is currently being developed by Alder BioPharmaceuticals.

Emgality successfully reduced Migraine attacks in patients with both episodic (more than 4 days a month) and Chronic Migraine, even among patients who had previously tried Botox without success. Results from Phase 3 trials were presented at the American Headache Society Scientific Meeting in June.

STUDY: EMGALITY PREVENTS EPISODIC AND CHRONIC MIGRAINE ATTACKS IN PATIENTS WHO FAILED BOTOX

Phase 3 results showed that patients with Chronic Migraine who did not respond to Botox and who were treated with **120 mg of Emgality had an average of 3.91 fewer Migraine days** compared to the placebo.

Those who received the larger dose, **240 mg, had 5.27 fewer Migraine days** compared to placebo (2)

Super-Responders. The study also measured the percentage of patients who had at least a 50% reduction in monthly Migraine days: **41.3% of those receiving 120 mg and 47.5% of those receiving 240 mg**, compared to 9.4% of placebo. In this analysis of patients who did not respond to Botox, patients treated with Emgality also had statistically significant improvements in quality of life, as measured by the Migraine-Specific Quality of Life Questionnaire (MSQ) and the Patient Global Impression of Severity (PGI-S) rating.

A Phase 3 trial for Emgality analyzed a subset of patients who did not respond to Botox. More than 40% of those patients had at least a 50% reduction in their Migraine days. Image: Storyblocs

These results, including the number of "super-responders" who have a substantial reduction in disability and Migraine days, are similar to those of other anti-CGRP drugs. This Emgality study, however, has the unique feature of looking at patients who failed Botox. This is promising for those with Migraine who have tried most of the available options and are eager for new treatments, like anti-CGRP meds.

Safety and Dosing

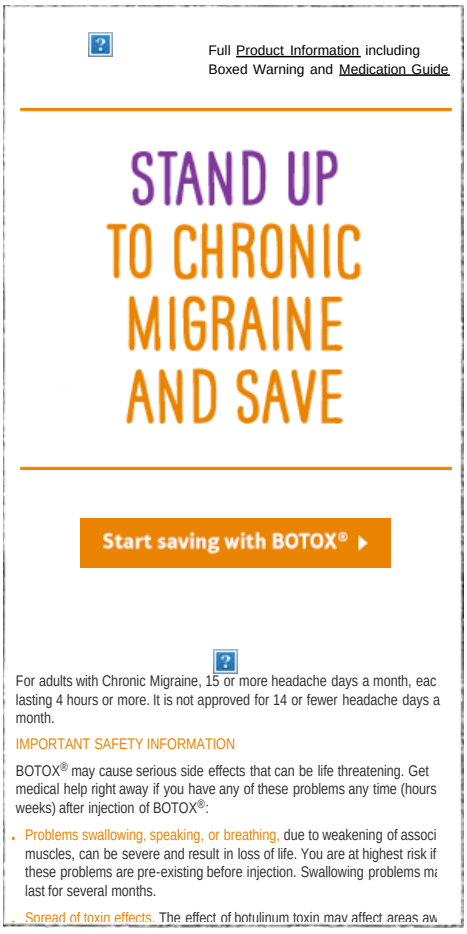
Summarizing the different anti-CGRP studies, Dr. Elizabeth Loder told *MedPage Today*,

> **"To me, the fascinating thing is they all look quite similar. I'm sure the individual companies would disagree, but to me, we're seeing pretty much across the board the same statistically significant — but let's face it, modest — reductions in number of headache days.**
>
> **I think the message with this class of medications is that they're very well tolerated."**

However, she noted that long-term safety remains uncertain, and safety during pregnancy is still a concern (3)

The recommended dose for Emgality is 240 mg (two consecutive subcutaneous injections of 120 mg each) once as a loading dose, followed by monthly doses of 120 mg injected subcutaneously.

The safety of Emgality was evaluated in three clinical trials that included more than 2,500 patients. Hypersensitivity reactions (e.g., rash, urticaria and dyspnea) have been reported with Emgality in clinical studies, can occur days after administration and may be prolonged. The most common adverse reactions (incidence ≥2% for Emgality and at least 2% greater than placebo) associated with Emgality treatment (120 mg vs. placebo) were injection site reactions (18% vs. 13%).



HOW TO ACCESS EMGALITY

The Coalition for Headache and Migraine Disorders (CHAMP) released a helpful guide to navigating the financial assistance programs. Access it here.

EMGALITY FOR CLUSTER HEADACHES: APPROVAL BY THE END OF THE YEAR?

The trials also showed that Emgality reduced episodic cluster headaches, but failed to produce results for chronic cluster headaches. Emgality is the only anti-CGRP treatment to produce positive Phase 3 results for cluster headaches.

The drug company is expected to file for FDA approval for cluster headache prevention by the end of this year.

As of press time, however, Emgality is only approved for the prevention of Migraine.

STUDY: EMGALITY PREVENTS EPISODIC CLUSTER HEADACHES

The episodic cluster headache trial included a total of 106 patients with an average of 17.5 cluster headache attacks per week at baseline. Patients were chosen at random to receive either once-monthly galcanezumab 300mg administered via injection or a placebo.

Results showed that the group receiving the drug saw a significant difference in the reduction of their weekly attacks compared with placebo. Between Weeks 1 and 3 of the two-month treatment period, those receiving Emgality experienced 8.7 fewer cluster headache days vs. 5.2 fewer days for placebo; (p=0.36), the primary endpoint for the study.

Three out of four participants (76%) who were treated with the drug had at least a 50% reduction in weekly cluster headache attacks compared to 57% for the placebo at Week 3, the secondary endpoint. Also, 73% of patients treated with Emgality reported improvements based on the Patient Global Impression of Improvement (PGI-I) at Week 4, compared to 46% for the placebo (4)

The observed safety and tolerability profile were consistent with previous studies that evaluated Emgality for the prevention of Migraine. As with other anti-CGRP drugs, the long-term effects and tolerability are not known.

CHRONIC CLUSTER HEADACHES ARE A DIFFERENT STORY

Chronic cluster headaches are proving difficult to treat. A competing anti-CGRP drug from Teva, Ajovy, also failed to prevent chronic cluster headaches. Cluster headaches, like Migraine, are not headaches at all but are a complex, neurological disease. The pain is debilitating and so severe they have been dubbed “suicide headaches.”

In an interview last year with Migraine Again, cluster headache warrior Tyler Mann said: “I am not a suicidal person, and I enjoy life. But when I am in the middle of a cluster attack, suicide is a real option that I have considered. The pain is more than anything you can imagine.” Despite the severity of cluster headache attacks, treatment options remain limited and difficult to access.

Emgality’s mixed results in preventing cluster headaches are bittersweet: on one hand, an effective preventative for clusters is incredibly valuable, but those who are most impacted by the disease are left disappointed. None of the anti-CGRP medications in trials have been able to prevent chronic cluster headaches.

WHAT’S NEXT?

this fee is expected to be reimbursed by health insurance companies in the US.

Eli Lilly expected to file for FDA approval for the prevention of cluster headaches by the end of 2018.

Patients and healthcare professionals with questions about Emgality should contact The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979) or 1-833-EMGALITY or visit www.lilly.com. Patients can also text INFO to 54559 to receive an injection how-to video and other helpful resources delivered straight to their phone.

COMMENTS? ARE YOU EAGER TO TRY ANTI-CGRP DRUGS LIKE EMGALITY?

Photo by Ravi Roshan on Unsplash

FOOTNOTES

1. Saganowsky, Eric. Lilly's third-to-market Emgality nets FDA 'breakthrough' in cluster headache. FierceFarma. 15 November 18.
2. AHS 2018: Lilly's Emgality™ (galcanezumab-gnlm) Significantly Reduced Monthly Migraine Headache Days in Patients with Migraine Who Previously Failed BOTOX®* (onabotulinumtoxinA). Press Release. 27 June 2018. Investor.lilly.com
3. Liz Highleyman. Galcanezumab Offers Hope for Cluster Headache and Migraine. AHS Meeting Coverage. MedPageToday. 03 July 2018.
4. AHS 2018: Lilly Highlights Positive Phase 3 Results from the Largest Controlled Preventive Trial in Episodic Cluster Headache. Press Release. 27 June 2018. Investor.Lilly.com

The Day After: Study on Stress, Relaxation and Migraine

On The Power of Gratitude (or, Why You Should Write That Thank You Note)

ABOUT THE AUTHOR

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Angie Glaser is the Content Editor of Migraine Again and author of the blog Chronic Migraine Life. She's a twice-nominated WEGO Health Advocate for her insightful writing, telling patient stories, Headache on the Hill advocacy and her bold voice o migraine disability. She's been featured on the Migraine World Summit and advised industry leaders on patient needs. Conne with her on Twitter, Facebook, Instagram and on her blog.

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