

News: Health, Clinical Trials, Neuroscience

What we know — and don't know — about a new migraine drug

Aimovig was recently approved for use by the U.S. Food and Drug Administration

By Leah Rosenbaum 2:17pm, June 5, 2018



HOPE FOR MIGRAINES? A new preventive treatment for migraines was recently approved by the U.S. Food and Drug Administration. kitzcorner/iStockphoto

Migraines have plagued humans since time immemorial. Now a new migraine prevention treatment, recently approved by the U.S. Food and Drug Administration, promises long-awaited relief from the debilitating condition. But whether the drug will turn out to be a real solution for the 1 in 7 Americans who suffer from migraines, severe headaches that often come with nausea and visual auras, isn't yet clear. Here's what we know, and don't know, about the new therapy.

How does the drug work in the body?

The new drug, <u>Aimovig</u>, generically called erenumab, is a type of monoclonal antibody treatment, a class of medications that resemble the antibodies that the body naturally produces to bind to infectious pathogens.

These treatments work by using specially designed antibodies to target specific proteins and their receptors that contribute to disease. Aimovig, released by pharmaceutical companies Amgen Inc. and Novartis, targets the receptor for a protein called calcitonin gene-related peptide, or CGRP, that is increased in people suffering a migraine attack.

The protein is released from nerve endings throughout the body, including in the meninges, the membranes that surround the brain. When it attaches to the receptor, CGRP widens blood vessels and can contribute to inflammation and pain transmission. Aimovig, delivered once a month with an EpiPenlike injector, works by blocking the receptor for CGRP, reducing pain.

Blocking the protein's receptor is kind of like putting gum in a lock, says Elizabeth Loder, a neurologist at Brigham and Women's Hospital in Boston and at Harvard Medical School. The CGRP protein "key" is still floating around, but it can't become activated.

Could the new drug be a better solution for migraine sufferers?

Most medications currently used to prevent migraines were created for other health issues, including high blood pressure, depression and epilepsy. Many of these drugs are only somewhat effective for migraines, and can have severe side effects including extreme drowsiness and brain fog. Unlike most current medications, Aimovig seems to have fewer daily side effects, which may mean that people take it more regularly and can stay on it for longer periods of time.

On average, Aimovig reduces the number of migraines by one to two each month, which is on par with current migraine medications. "It would be great if we had a new treatment that works substantially better than the treatments we now have," says Loder, "but that is not the case here."

There is also a potential barrier to Aimovig: cost. Amgen and Novartis are currently offering two free doses to eligible patients, but after that the medication costs \$6,900 per year for people paying out of pocket.

What questions remain about the drug?

Because Aimovig is new, there's much researchers don't know about it. Long-term effects on people, for example, will have to be followed closely, says Matthew Robbins, a neurologist at Montefiore Medical Center in New York City. This is especially crucial in chronic migraine patients, who may be taking the medication for decades.

And as with many types of drugs, scientists don't know how the medication will affect pregnant women (SN Online: 5/30/18). The FDA isn't telling pregnant women not to use the drug, but the agency is making Amgen monitor for the next several years outcomes in pregnant women who use the drug. The drug can take some time to clear the body, so women who are trying to conceive and don't want Aimovig in their system should discontinue treatment at least five months before becoming pregnant, says neurologist David Dodick of the Mayo Clinic in Phoenix. Dodick participated in the design and analysis of the Aimovig clinical trials.

There is also uncertainty about whether the drug will have side effects for people with cardiovascular issues, such as high blood pressure or coronary artery disease. Sometimes, CGRP can be good for the body — the protein helps relax arteries, including around the heart, and leads to better blood flow and a lower heart rate. The bodies of people taking Aimovig, a CGRP receptor blocker, may not be able to perform these essential functions in a cardiovascular emergency.

There is a theoretical risk that blocking CGRP's action could lead to a heart attack or stroke, Dodick says, but that hasn't been observed in any of the thousands of patients who have been treated in clinical trials.

Are there other similar drugs being developed?

Aimovig is the first CGRP monoclonal antibody treatment to be approved by the FDA, but it might not be alone for long. Eli Lilly, Teva Pharmaceutical Industries and Alder Biopharmaceuticals are all in the

midst of clinical trials for similar drugs. Instead of targeting CGRP's receptor, these medications target the protein itself. They will also be delivered by differing mechanisms: Some, like Aimovig, will be given via injection, while others might need to be administered through an infusion at the hospital.

Citations

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Further Reading

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