About Aimovig[®] (erenumab) in migraine prevention Media factsheet

About migraine

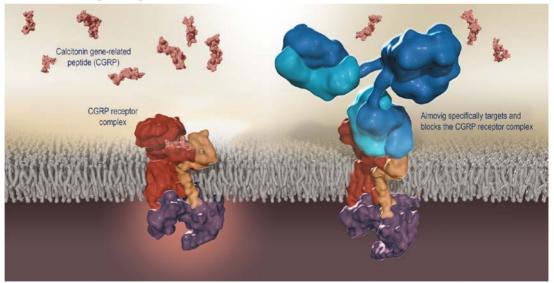
Migraine is a distinct neurological disease¹. It involves recurrent attacks of moderate to severe head pain and may be associated with nausea, vomiting and sensitivity to light, sound and odors². It is one of the top 10 causes of years lived with disability for men and women according to the World Health Organisation³. It remains under-recognized and under-treated¹.

People with migraine are in urgent need of new preventive treatment options as up to 80% of patients with chronic migraine discontinue preventive medication within a year⁴. Furthermore, currently available preventive treatments have generally been repurposed from other areas rather than designed with migraine as a target². Also, most available treatments aim to relieve symptoms rather than prevent migraine attacks. Frequent use of medications to treat headaches when they occur can lead to medication-overuse headache which can result in entering a destructive cycle of medication use⁵.

About Aimovig[®]

Overview

Aimovig has been approved by the US Food and Drug Administration, the European Medicines Agency, the Australian Therapeutic Goods Administration and Swissmedic. It is a novel therapeutic approach, the first and only medication specifically developed to prevent migraine by blocking the calcitonin gene-related peptide receptor (CGRP-R), which is believed to play a critical role in migraine⁶. Aimovig is self-administered or can be administered by another trained person once every four weeks via an autoinjector pen and does not require a loading dose. Some patients may benefit from a dosage of 140 mg once every four weeks.



How is Aimovig thought to work?

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CGRP is a protein that binds to the CGRP receptor complex and is thought to be responsible for transmitting the pain signals associated with migraine⁶. In people with migraine, CGRP levels increase at the onset of pain and return to normal when migraine pain subsides⁷.

Aimovig specifically blocks the CGRP receptor. It is the first and only fully human monoclonal antibody of its kind designed to do this.



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What is the clinical evidence?

Data from clinical trials on Aimovig involving more than 3,000 patients have shown meaningful and sustained benefits in patients across the spectrum of migraine including reduced migraine days, even in difficult-to-treat patients⁸⁻¹¹.

How was Aimovig developed?

Aimovig is being co-developed by Novartis and Amgen. In August 2015, Novartis entered into a global collaboration with Amgen to develop and commercialize pioneering treatments in the field of migraine and Alzheimer's disease. The collaboration focuses on investigational Amgen drugs in the migraine field, including Aimovig and AMG 301 (currently in Phase II development). In April 2017, the collaboration was expanded to include co-commercialization of Aimovig in the United States. For the migraine program, Amgen retains exclusive commercialization rights in Japan, and Novartis has exclusive commercialization rights in Europe, Canada and rest of world.

References

- 1. Migraine Research Foundation. Migraine Fact Sheet. 2015. http://www.migraineresearchfoundation.org/fact-sheet.html. Accessed July 2018.
- National Institute for Neurological Disorders and Stroke. https://www.ninds.nih.gov/Disorders/All-Disorders/Migraine-Information-Page. Accessed July 2018.
- 3. World Health Organization. Headache disorders. http://www.who.int/mediacentre/factsheets/fs277/en/. Accessed May 2018.
- 4. Hepp Z, et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. Cephalalgia. 2015; 35(6):478-88.
- 5. Headache Classification Committee of the International Headache Society, 2013
- 6. Bigal ME et al. Calcitonin gene-related peptide (CGRP) and migraine: Current understanding and state of development. Headache. 2013;53(8):1230-1244.
- 7. Lassen et al. CGRP may play a causative role in migraine. Cephalalgia. 2002 Feb;22(1):54-61. http://www.ncbi.nlm.nih.gov/pubmed/11993614.
- 8. Dodick DW et al. ARISE: A phase 3 randomized trial of erenumab for episodic migraine. Cephalalgia. 2018 Jan 1:333102418759786
- Goadsby PJ et al. A controlled trial of erenumab for episodic migraine. N Engl J Med. 2017 Nov 30;377(22):2123-2132.
- 10. Tepper S et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. Lancet Neurol. 2017 Jun;16(6):425-434.
- Reuter U et al. Efficacy and safety of erenumab in episodic migraine patients with 2–4 prior preventive treatment failures: Results from the Phase 3b LIBERTY study. Emerging science abstract presented at AAN, 24 April 2018, Los Angeles.

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Novartis Pharma AG Novartis Campus CH-4056 Basel Switzerland

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