

About erenumab (AMG 334) in migraine prevention

Media factsheet

About migraine

Migraine is a distinct neurological disease.¹ 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.

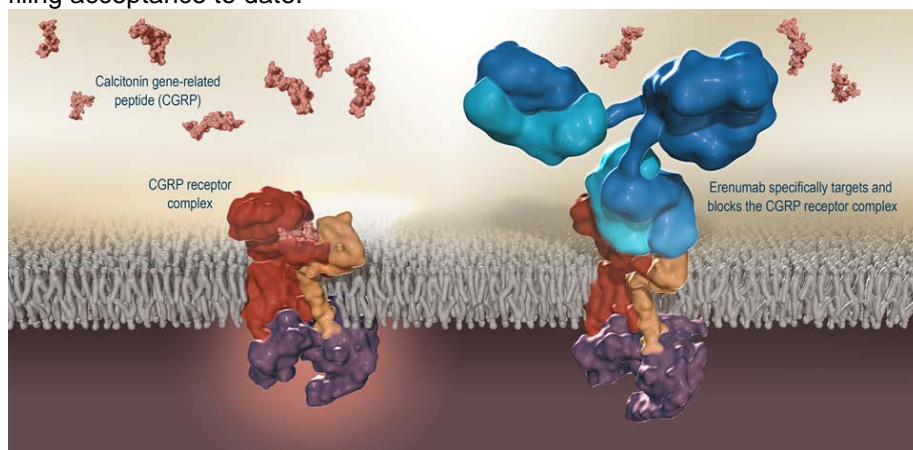
People with migraine are in urgent need of new preventive treatment options as up to 80% of chronic migraine patients discontinue preventive medication within a year⁴. Furthermore, currently available preventive treatments have generally been repurposed from other areas rather than designed with migraine as a target². Additionally, most available treatments aim to relieve rather than prevent migraine. 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 erenumab (AMG 334)

Overview

Erenumab is the first and only fully human monoclonal antibody of its kind, designed to specifically block the CGRP receptor, which plays a critical role in migraine activation⁶.

Erenumab (AMG 334) is being co-developed by Novartis and Amgen. In April 2017, this collaboration was expanded to include co-commercialization of AMG 334 (erenumab) in the U.S. For the migraine program, Amgen retains sole commercialization rights in Japan, and Novartis has commercialization rights in Europe, Canada and rest of world. Erenumab is the first and only drug targeting the CGRP pathway to have received FDA and EMA regulatory filing acceptance to date.



How is erenumab thought to work?

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.

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

What is the clinical evidence?

Data from clinical trials on erenumab involving more than 2,600 patients have shown meaningful and sustained benefits in patients with migraine including reduced migraine days^{8,9}.



References

1. Migraine Research Foundation. Migraine Fact Sheet. 2015. <http://www.migraineresearchfoundation.org/factsheet.html>. Accessed April 2017.
2. National Institute for Neurological Disorders and Stroke. <https://www.ninds.nih.gov/Disorders/All-Disorders/Migraine-Information-Page> (link is external). Accessed April 2017.
3. World Health Organization. Headache disorders. <http://www.who.int/mediacentre/factsheets/fs277/en/>. Accessed August 2016.
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. A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Erenumab in Migraine Prevention: Primary Results of the ARISE Trial. *Headache*. 2017. Jun; 57(S3):191
9. 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.