

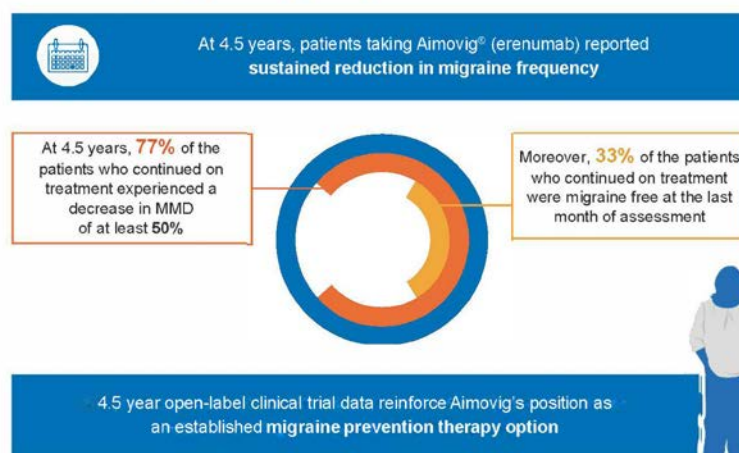
**MEDIA UPDATE • MEDIA UPDATE • MEDIA UPDATE**

## **Novartis data confirm long-term efficacy and safety of Aimovig® for majority of patients with episodic migraine**

- *The 5-year open-label treatment period (OLTP) examines sustained efficacy and long-term safety of Aimovig® (erenumab) in patients with episodic migraine, starting on 70mg and switched after two years to 140mg*
- *4.5-year data show 77% of the patients who continued on treatment experienced at least a 50% reduction in monthly migraine days (MMD) at the last month of assessment*
- *Moreover, 33% of patients who continued on treatment achieved a 100% reduction, and 56% achieved a 75% decrease in MMD*
- *These additional long-term data complement Aimovig's position as the most prescribed anti-CGRP, with more than 250,000 patients prescribed worldwide since launch<sup>1</sup>*

**Basel, September 09, 2019** – “We are pleased to see that during the OLTP, Aimovig® was not only able to reduce monthly migraine days, but also decrease the number of days requiring acute migraine-specific medication” said Estelle Vester-Blokland, Global Head Neuroscience Medical Affairs, Novartis Pharmaceuticals. “These 4.5-year data further add to Aimovig’s established benefit for people living with migraine. Novartis is committed to reimagining migraine care, by providing patients with an effective preventive treatment option so that they may take their lives back from this highly debilitating disease.”

**5-year open-label extension study evaluating the long-term safety and efficacy of Aimovig® in episodic migraine patients experiencing between 4 and 14 monthly migraine days (MMD)**



### **About the Open-Label Treatment Period (OLTP) in Episodic Migraine**

This is a 4.5-year, interim analysis of a 5-year, open-label treatment period (OLTP) in patients with episodic migraine (NCT01952574) to evaluate the sustained efficacy and long-term safety of Aimovig in patients taking 70mg and 140mg. In the OLTP, patients initially received 70mg of Aimovig monthly. The dose was increased to 140mg for the patients continuing the study after ~2 years. Of the 250 patients who switched from Aimovig 70mg to 140mg, 221 patients (88%) completed the OLTP or remained on 140mg at 4.5 years. From a baseline of 8.7 [2.7] and 6.1 [2.7] days, a change of - 5.8 [3.8] and - 4.6 [3.3] was observed for monthly migraine days and acute migraine-specific medication treatment days respectively. Efficacy endpoints for the OLTP included change in monthly migraine days and change in acute migraine-specific medication treatment days from baseline. The safety analysis was performed by evaluating the exposure-adjusted incidence rate of adverse events data of the 12-week short-term studies and the OLTP of up to 4.5 years. No new safety signals were observed for Aimovig, whose safety profile and tolerability were in line with previous clinical trial data.

### **About Aimovig (erenumab)**

Aimovig is the first EMA, Swissmedic, Australian TGA and FDA-approved migraine prevention treatment designed specifically to block the calcitonin gene related peptide receptor (CGRP-R), which plays a critical role in migraine. Aimovig has been studied in several large, global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention. More than 3,000 patients have participated in our overall clinical trial program. This includes 2,600 participants across the four placebo-controlled pivotal Phase II and Phase III clinical studies as well as participants in further studies such as LIBERTY, a dedicated study in a difficult-to-treat treatment failure population. The most common side effects in the clinical program to date have been viral upper respiratory tract infection, upper respiratory tract infection, sinusitis, influenza, and back pain.

Novartis and Amgen are co-commercializing Aimovig in the US. Amgen has exclusive commercialization rights to the drug in Japan and Novartis has exclusive rights to commercialize in the rest of the world.

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### **References**

1. Messoud A, et al. Sustained efficacy and long-term safety of erenumab in patients with episodic migraine: 4+ year results of a 5-year. IHC 2019.

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