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MEDIA UPDATE

Novartis announces new publication in *Cephalalgia* of data showcasing superior tolerability and efficacy of Aimovig® (erenumab) compared with topiramate in migraine prevention

- *HER-MES, a Phase IV study, is the first and only randomized, double blind, head-to-head study that compares an antibody targeting the CGRP pathway, Aimovig® (erenumab), with an oral prophylactic migraine treatment (topiramate)*[1]

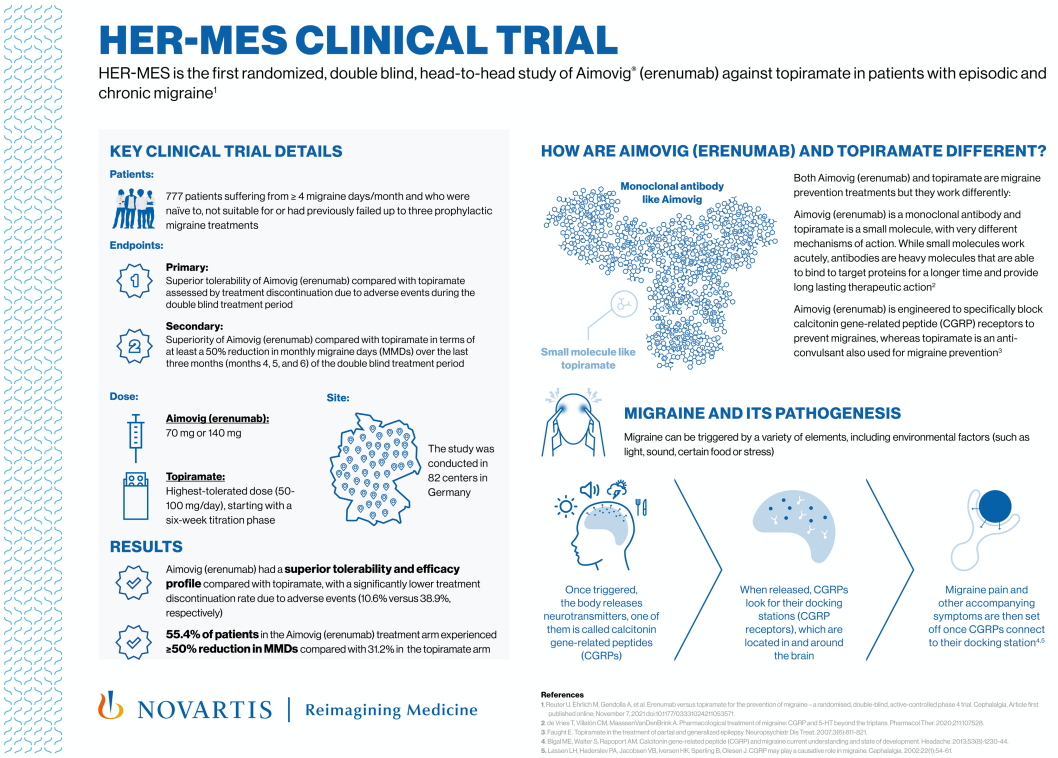
- *Aimovig demonstrated superior tolerability and efficacy against topiramate, with 55.4% of patients in the Aimovig group achieving a reduction in monthly migraine days of at least 50% from baseline compared with 31.2% in the topiramate group*[1]

- *Aimovig is the most utilized anti-CGRP treatment, with more than half a million patients prescribed worldwide since launch*[2]

Basel, November 8, 2021 — Novartis announced today that data from HER-MES has been published in *Cephalalgia*[1]. This is the first and only randomized, double blind, double-dummy, active-controlled, parallel-group Phase IV study of Aimovig (erenumab) against topiramate, an anticonvulsant, in patients with episodic and chronic migraine. Results showed that Aimovig had a superior tolerability profile compared with topiramate, with a significantly lower treatment discontinuation rate due to adverse events (10.6% with Aimovig® vs 38.9% with topimarate)[1]. Aimovig also demonstrated superior efficacy against topiramate, with patients having a significantly higher probability of achieving a clinically meaningful improvement in migraine frequency when they were randomized to Aimovig compared to topiramate (55.4% vs 31.2%)[1]. The positive outcomes in the Aimovig group translated into a major improvement in quality of life and in functional impairment for the patients.

“HER-MES is the first study that directly compared the therapeutic effect of an antibody and a small molecule in migraine prevention,” said Prof. Uwe Reuter, Managing Medical Director at Charité Universitätsmedizin. “The positive outcomes strengthen the position of erenumab as a safe and effective migraine prevention treatment that can significantly enhance quality of life for migraine patients with an improved dosing regimen.”

“Results of this first and only head-to-head study show superior tolerability and efficacy for Aimovig versus topiramate, further demonstrating the value of Aimovig to patients living with migraine,” said Lykke Hinsch Gylvin, Neuroscience Global Medical Franchise Head, Novartis Pharmaceuticals. “We are proud to continue reimagining migraine care by providing a safe and effective preventive treatment option to patients living with this highly debilitating disease.”



About HER-MES

HER-MES (NCT03828539) is a randomized, double blind, double-dummy, active-controlled, parallel-group Phase IV study to assess the tolerability and efficacy of Aimovig® (erenumab) versus topiramate in a patient-centered setting[1]. The primary endpoint was treatment discontinuation rate due to adverse events of 70 mg and 140 mg erenumab compared with 50–100 mg/day topiramate during the double blind treatment phase of the study[1]. The secondary endpoint was efficacy of 70 mg and 140 mg erenumab versus the highest-tolerated dose (50-100 mg daily) of topiramate in terms of at least a 50% reduction in monthly migraine days (MMDs) from baseline in the last three months (Months 4, 5 and 6) of the double blind, 24-week treatment phase[1]. The HER-MES study enrolled 777 adult patients with episodic or chronic migraine (≥4 migraine days per month) who had not previously received migraine prevention treatment or had failed three previous therapies with propranolol/metoprolol, amitriptyline and flunarizine[1]. After a two-week screening and four-week baseline phase, patients were randomized 1:1 to erenumab or topiramate. In the double blind, 24-week treatment phase, patients in the erenumab arm received either 70 mg or 140 mg directly after the baseline phase[1]. An increase in dose from 70 mg to 140 mg was possible at any time during the study. Patients in the topiramate arm were given topiramate at the highest-tolerated dose (50-100 mg), starting with a six-week titration phase[1]. The study was conducted at 82 study sites in Germany between February 2019 and July 2020.

About Aimovig® (erenumab)

Aimovig is the first European Medicines Agency (EMA), Swissmedic, and U.S. Food and Drug Administration (FDA)-approved migraine prevention treatment designed specifically to block the anti-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 over 2,600 patients across the four placebo-controlled, Phase II and Phase III clinical studies as well as participants in further studies such as LIBERTY, a dedicated study in a treatment failure population that is difficult to treat[3]. The most common side effects in the clinical program to

date have been viral upper respiratory tract infection, sinusitis, influenza and back pain. Aimovig is the most utilized anti-CGRP treatment worldwide, with more than 520,000 patients prescribed in the post-trial setting[1].

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.

About Migraine
Migraine is a distinct neurological disease[4]. It involves recurrent attacks of moderate-to-severe head pain that is typically pulsating, often unilateral and associated with nausea, vomiting and sensitivity to light, sound and odors[5]. Migraine is associated with personal pain, disability, reduced quality of life and financial cost to society[6]. It has a profound and limiting impact on an individual's ability to carry out everyday tasks. The World Health Organization reported migraine to be one of the top 10 causes of years lived with disability for men and women[6,7]. It remains under-recognized and under-treated[6,8].

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About Novartis
Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding

innovative ways to expand access to our latest treatments. About 108,000 people of more than 140 nationalities work at Novartis around the world. Find out more at https://www.novartis.com.

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