Novartis data show Aimovig® cuts acute migraine medication days by half in patients who failed prior preventive therapies

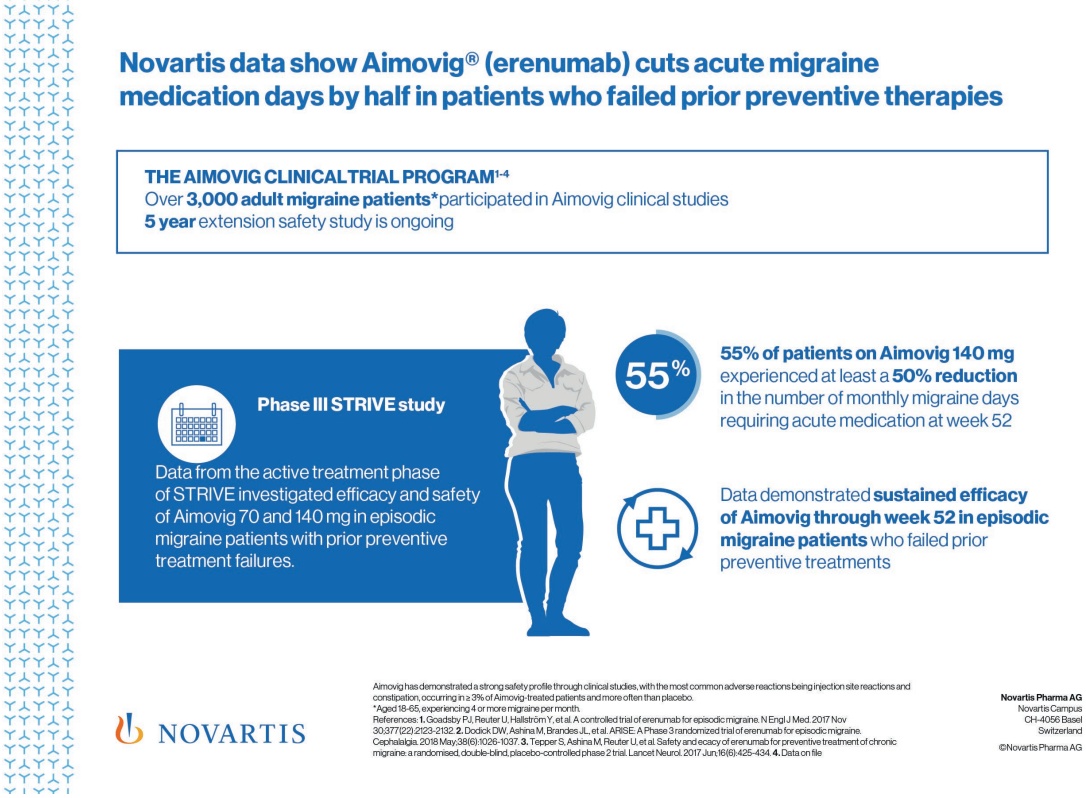
- *Data from the active treatment phase of STRIVE investigated efficacy and safety of Aimovig (erenumab) 70 and 140 mg in episodic migraine patients with prior preventive treatment failures*

- *STRIVE data show that 55% of patients on Aimovig 140 mg experienced at least a 50% reduction in the number of monthly migraine days requiring acute medication at week 52*

- *Data demonstrated sustained efficacy of Aimovig through week 52 in episodic migraine patients who failed prior preventive treatments; reinforcing Novartis' commitment to reimagine medicine for patients across the spectrum of migraine*

- *The additional long-term data in a population with prior treatment failures complement Aimovig's position as the most prescribed anti CGRP, with more than 220,000 patients prescribed worldwide since launch*[1]

Basel, July 1, 2019 — Novartis, a global leader in Neuroscience, today announced that new data from the active treatment phase (ATP) of the STRIVE Phase III clinical study will be presented at the European Academy of Neurology (EAN) annual meeting in Oslo, Norway. These additional data demonstrate Aimovig® (erenumab) 70 mg and 140 mg significantly reduced monthly migraine days (MMD) and migraine-specific medication days (MSMD) for episodic migraine patients who have previously struggled to find effective and tolerable preventive therapies specifically designed for migraine prevention. These findings add to the breadth of clinical data which show the sustained efficacy of Aimovig across the spectrum of migraine, including in those who have failed prior preventive treatments.



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About STRIVE
STRIVE (Study to Evaluate the Efficacy and Safety of Erenumab in Migraine Prevention, NCT02456740) is a global Phase III, multicenter, randomized 24-week, double-blind, placebo-controlled study evaluating the safety and efficacy of Aimovig in episodic migraine (characterized in this study as >=4 to <15 migraine days per month and <15 headache days per month on average across the three months before screening) prevention. In the study, 955 patients were randomized to receive once-monthly subcutaneous placebo, or Aimovig (70 mg or 140 mg) in a 1:1:1 ratio. Patients experienced between four and 14 migraine days each month, with an average of 8.3 migraine days per month at baseline. The primary endpoint was change in mean monthly migraine days from baseline over the last three months of the double-blind treatment phase of the study (months 4, 5 and 6)[2]. Secondary study endpoints assessed included reduction of at least 50% from baseline in mean MMD, change from baseline in mean monthly acute migraine-specific medication days, and changes from baseline in both mean impact on everyday activities domain and mean physical impairment domain scores on the Migraine Physical Function Impact Diary (MPFID)[2].

At week-24 (ATP baseline), 845 patients were re-randomized (1:1) to Aimovig 70 mg or 140 mg for the subsequent 28-week dose-blinded ATP. Assessments included MMD; monthly acute migraine specific medication days (MSMD); proportion of patients achieving a >=50%, >=75%, and 100% reduction in MMD (responder rates: RR); and safety[3]. The safety of Aimovig was assessed for both doses and showed consistent results with previous data[4], with the most common adverse reaction being injection site reactions[2].

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.

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 more than 750 million people globally and we are finding innovative ways to expand access to our latest treatments. About 105 000 people of more than 140 nationalities work at Novartis around the world. Find out more at **www.novartis.com**.

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Novartis Global External Communications
E-mail: media.relations@novartis.com

Antonio Ligi
Novartis External Communications
+41 79 723 3681 (mobile)
antonio.ligi@novartis.com

Eric Althoff
Novartis US External Communications
+1 646 438 4335
eric.althoff@novartis.com

Friedrich vonHeyl
Novartis Global Pharma Communications
+41 61 324 8631(direct)
+41 79 752 6955 (mobile)
friedrich.vonheyl@novartis.com