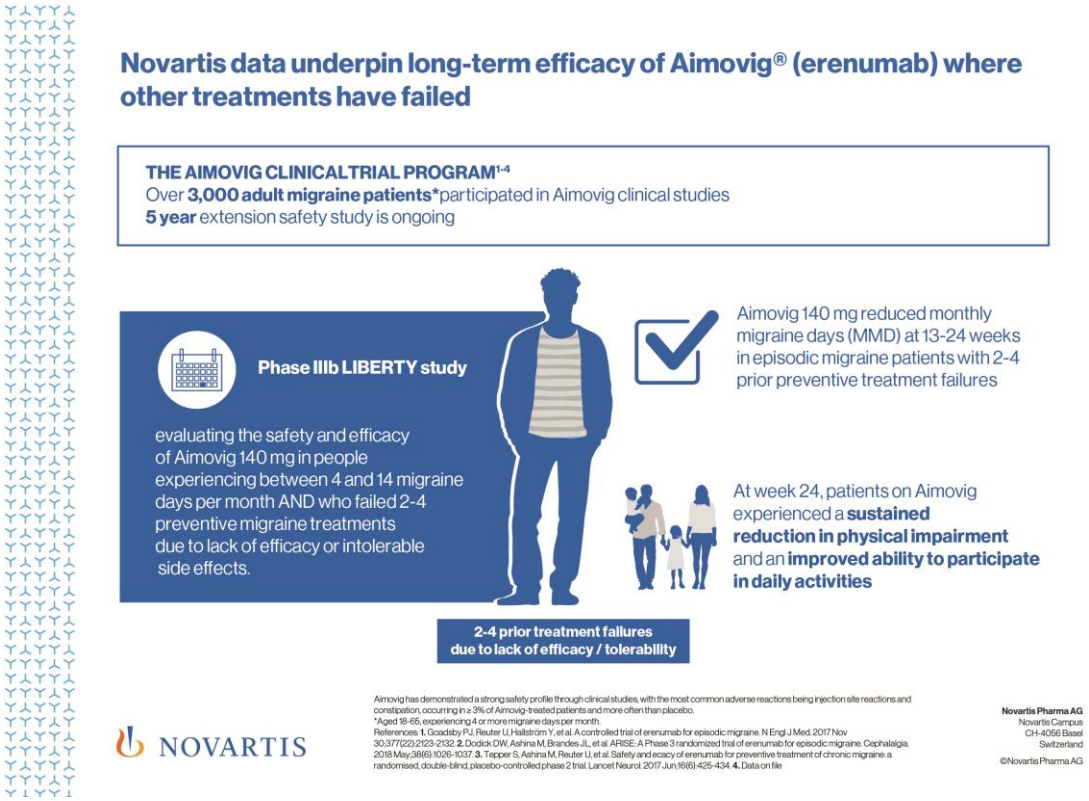
Novartis data underpin long-term efficacy of Aimovig® where other treatments have failed

- *Data from LIBERTY demonstrated sustained efficacy of Aimovig (erenumab) 140 mg in reducing monthly migraine days (MMD) at 13-24 weeks in episodic migraine patients with 2-4 prior preventive treatment failures*
- *At week 24, patients on Aimovig experienced a sustained reduction in physical impairment and an improved ability to participate in daily activities*
- *Breadth of data in patients with prior treatment failures presented at EAN reinforces Novartis' commitment to reimagining medicine for migraine patients across the spectrum of the disease*
- *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 additional data of the LIBERTY Phase IIIb study will be presented at the 2019 European Academy of Neurology (EAN) annual meeting in Oslo, Norway. This open-label extension phase (OLEP) confirms Aimovig® (erenumab) 140 mg decreases the number of MMD as well as migraine-specific medication days (MSMD). Patients who initiated Aimovig during the OLEP demonstrated rapid improvement in weeks 13-16 and weeks 21-24 on all efficacy parameters. Outcomes on patients' physical impairment and ability to participate in daily activities were also assessed and showed improvement (Headache Impact Test-6 [HIT-6™] and Migraine Physical Function Impact Diary [MPFID]).

"This new set of data results underline the long-term efficacy of Aimovig for patients who have struggled to find effective preventive therapies specifically designed for migraine," said Danny Bar-Zohar, Global Head, Neuroscience Development for Novartis Pharmaceuticals. "Being able to propose additional solutions, such as Aimovig, for patients with prior preventive treatment failures is key to help them get their lives back."



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About LIBERTY
LIBERTY (NCT03096834) is a Phase IIIb, multicenter, randomized 12-week, double-blind, placebo-controlled study evaluating the safety and efficacy of erenumab in patients with episodic migraine (defined in the trial as four to 14 migraine days per month at baseline) who have failed two to four prior preventive treatments for migraine[2]. In the study, 246 participants were randomized to receive erenumab140 mg or placebo during the 12-week double-blind treatment phase (DBTP). The primary endpoint was the percentage of patients with at least 50% reduction of monthly migraine days from baseline over the last four weeks of the DBTP of the study (weeks 9-12).

Secondary endpoints assessed during the same time period included: change from baseline in monthly migraine days, change from baseline in the number of monthly acute migraine-specific medication treatment days, change from baseline in the Migraine Physical Function Impact Diary (MPFID) physical impairment and impact on everyday activities domain scores. The MPFID is a scale developed to measure these two domains. It has been validated in line with US Food and Drug Administration Patient Reported Outcomes Guidance[3]. Percentages of patients with a 75% response rate and 100% response rate to erenumab, and safety and tolerability were also assessed as secondary endpoints. The most common adverse events observed in LIBERTY were injection site pain (5.9%), back pain (4.2%) and nasopharyngitis (4.2%).

The trial includes an ongoing 156 weeks open label extension phase (OLEP) to assess the long-term efficacy of erenumab. Patients who completed the 12-week DBTP were enrolled in the 156 weeks OLEP. Patients already on erenumab in the DBTP continued to receive erenumab 140 mg in the OLEP, while, those on placebo in the DBTP initiated erenumab 140 mg during the OLEP.

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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2. Reuter U. et al. 2018 Lancet; 392(10161):2280-2287
3. Kawata AK. et al. 2017. Headache; 57(9):1385-1398.

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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