# Aimovig<sup>®</sup> (erenumab) Clinical Trials **By The Numbers**

Aimovig<sup>®</sup> (erenumab) is the first and only FDA-approved treatment specifically developed to prevent migraine by blocking the calcitonin gene-related peptide receptor (CGRP-R), which is believed to play a critical role in migraine. It has been studied in several large, global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention.

#### **THE AIMOVIG CLINICAL TRIAL PROGRAM<sup>1-4</sup>**

- Over 3,000 adult migraine patients\* participated in Aimovig clinical studies 5 year extension safety study is ongoing
- · Safety profile of Aimovig was similar to placebo across the clinical trial program

#### STRIVE<sup>1</sup> Phase III Study



STRIVE (NCT02456740) is a 6-month Phase III

study evaluating the safety and efficacy of Aimovig 70mg and 140mg in people experiencing between four and 14 migraine days per month.\*\*



**121** clinical trial sites in 13 countries



**PRIMARY ENDPOINT MET** -3.2 and -3.7 migraine days per month with Aimovig at 70mg and 140mg doses respectively, -1.8 migraine days per month for placebo (p<0.001 for both doses vs. placebo)

## **ARISE<sup>2</sup> Phase III Study**



ARISE (NCT02483585) is a 3-month Phase III

study evaluating the safety and efficacy of Aimovig 70mg in people experiencing between four and 14 migraine days per month.\*\*\*



## **76** clinical trial sites in 8 countries



Enrolled **577** patients with an average of 8 migraine days per month at baseline

PRIMARY ENDPOINT MET -2.9 migraine days per month with Aimovig 70mg, -1.8 migraine days per month for placebo (p<0.001 vs. placebo)

## Chronic Migraine — Phase II Study<sup>3</sup>

The Pivotal Phase II (NCT02066415)



**3-month** study is evaluating the safety and efficacy of Aimovig 70mg and 140mg in people experiencing 15 or more migraine days per month.\*\*\*

**69** clinical trial sites in 10 countries

Enrolled 667 people

## with an average of 18 migraine days per month at baseline

## **PRIMARY ENDPOINT MET**

-6.6 migraine days per month with Aimovig at both doses (70mg and 140mg), **-4.2** migraine days per month for placebo (p<0.001 for

#### LIBERTY<sup>5</sup> Phase IIIb Study: the first study to investigate a treatment targeting the CGRP pathway specifically in patients who had failed 2 to 4 prior preventive treatments



LIBERTY (NCT03096834) is a 12-week Phase IIIb study evaluating the safety and efficacy of Aimovig 140mg in people experiencing between four and 14 migraine days per month AND who failed 2-4 preventive migraine treatments due to lack of efficacy or intolerable side effects\*\*\*

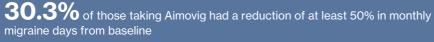


65 clinical trial sites in 16 countries



Enrolled 246 patients with an average of 9.3 migraine days per month at baseline

#### PRIMARY ENDPOINT MET



compared to **13.7%** of those taking placebo (p<0.001, odds ratio 2.73)

ALL SECONDARY ENDPOINTS MET INCLUDING



with Aimovig at 140mg. -0.15 migraine days per month for placebo

- Aged 18-65, experiencing 4 or more migraine days per month
- All endpoint assessments for STRIVE compared baseline to the last three months of the 6-month treatment phase
- \*\*\* All endpoint assessments for ARISE, the Phase II study and LIBERTY compared baseline to the last month of the 3-month treatment phases.

#### REFERENCES

1. Goadsby PJ et al. Trial of erenumab for episodic migraine. N Engl J Med. 2017 Nov 30:377(22):2123-2132

- 2. Dodick DW et al. ABISE: A Phase 3 randomized trial of erenumab for episodic migraine. Cephalalgia 2018 Jan 1:333102418759786
- 3. 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.

#### 4.Data on file

5. Reuter, U et al. Efficacy and safety of erenumab in episodic migraine patients with 2-4 prior preventive treatment failures: Results from the Phase 3b LIBERTY study. Emerging science abstract presented at AAN, 24 April 2018, Los Angeles

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