Aimovig® (erenumab) Clinical Trials

By The Numbers

Aimovig is approved in the EEA, the US, Canada, Australia, Switzerland, the UAE and Singapore. It is 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.

THE AIMOVIG CLINICAL TRIAL PROGRAM[1-4]

- 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[1] Phase III Study

STRIVE (NCT02456740) is a **6-month** Phase III study evaluating the safety and efficacy of Aimovig 70mg and 140mg in peopel experiencing between four and 14 migraine days per month.**

121 clinical trial sites in **13 countries**

Enrolled **955** patients with an average of **8.3** migraine days per month at baseline

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[2] 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[3]

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 both doses vs. placebo)

AIMOVIG CLINICAL TRIAL PROGRAM: ADDITIONAL STUDY

LIBERTY Phase IIIb Study[5]

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

30% of those taking Aimovig had a reduction of at least 50% in monthly migraine days from baseline compared to **14%** of those taking placebo (p<0.002, odds ratio 2.7)

ALL SECONDARY ENDPOINTS MET INCLUDING

-1.8 migraine days per month with Aimovig at 140mg. **-0.2** migraine days per month for placebo (p=0.004 vs. 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, Reuter U, Hallström Y, et al. A controlled trial of erenumab for episodic migraine. N Engl J Med. 2017 Nov 30;377(22):2123-2132.
2. Dodick DW, Ashina M, Brandes JL, et al. ARISE: A Phase 3 randomized trial of erenumab for episodic migraine. Cephalalgia. 2018 May;38(6):1026-1037.
3. Tepper S, Ashina M, Reuter U, 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, Goadsby PJ, Lanteri-Minet M, et al. Efficacy and tolerability of erenumab in episodic migraine patients who previously failed 2-4 preventive treatments. Lancet. 2018 Oct.

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