Erenumab (AMG 334) Clinical Trials

By The Numbers

Erenumab, the first anti-CGRP receptor drug designed to prevent migraine, has been studied in several large, global, randomized, double-blind, placebo-controlled studies to assess its safety and efficacy in migraine prevention.



THE ERENUMAB CLINICAL TRIAL PROGRAM¹⁻⁴

- Over 3,000 adult migraine patients* participated in erenumab clinical studies
- 5 year extension safety study is ongoing
- Safety profile of erenumab (AMG 334) was similar to placebo across the clinical trial program

STRIVE¹ Phase III Study



STRIVE (NCT02456740) is a

6-month Phase III study evaluating the safety and efficacy of erenumab 70mg and 140mg in people 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 erenumab at 70mg and

140mg doses respectively, **-1.8** migraine days per month for placebo (p<0.001 for both doses vs. placebo)

ARISE² Phase III Study



ARISE (NCT02483585) is a

3-month Phase III study evaluating the safety and efficacy of erenumab 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 erenumab 70mg, **-1.8** migraine days per month for placebo (p<0.001 vs. placebo)

Chronic Migraine — Phase II Study³



The Pivotal Phase II (NCT02066415)

3-month study is evaluating the safety and efficacy of erenumab 70mg and 140mg in people experiencing 15 or more migraine days



69 clinical trial sites in 10 countries

per month.***



Enrolled 667 people with an average of 18 migraine days per month at baseline

PRIMARY ENDPOINT MET

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

ERENUMAB CLINICAL TRIAL PROGRAM: ADDITIONAL STUDY

LIBERTY Phase IIIb Study⁵



LIBERTY (NCT03096834) is a 12-week Phase IIIb study evaluating the safety and efficacy of erenumab 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

30.3% of those taking erenumab had a reduction of at least 50% in monthly migraine days from baseline

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

ALL SECONDARY ENDPOINTS MET INCLUDING

-1.76 migraine days per month

with erenumab at 140mg. **-0.15** 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 et al. Trial of erenumab for episodic migraine. N Engl J Med. 2017 Nov 30;377(22):2123-2132.
- Dodick DW et al. ARISE: 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.

