Erenumab (AMG 334) Pivotal 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 primary endpoint for each study assessed mean changes in monthly migraine days from baseline compared to placebo.

THE ERENUMAB CLINICAL TRIAL PROGRAM¹⁻⁴

- Over 2,800 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 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 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 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 erenumab at both doses (70mg and 140mg), -4.2 migraine days per month for placebo (p<0.001 for both doses 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 and the Phase II study 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. A Phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of erenumab in migraine prevention: primary results of the ARISE trial. Headache. 2017. Jun; 57(S3): 191
- 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

