Efficacy and Safety of Erenumab 70 mg in Adult Patients with Chronic Migraine: Results from a Phase 3, Randomized, Double-Blind, Placebo-Controlled DRAGON Study

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Objective:
DRAGON is a 12-week phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of once-monthly subcutaneous erenumab 70 mg in adult patients with chronic migraine (CM).

Background:
DRAGON study (NCT03867201) enrolled patients from China and other Asian countries that were not adequately represented in the global CM pivotal study (NCT02066415).

Design/Methods:
Eligible patients with CM (N=557) were randomized (1:1) to receive either erenumab 70 mg or placebo for 12 weeks. The primary endpoint was change from baseline in monthly migraine days (MMD). The secondary endpoints were proportion of patients with ≥50% reduction in MMD, change in monthly acute headache medication days, modified migraine disability assessment scores (mMIDAS), and safety. Assessments were done over the last 4 weeks of the double-blind treatment period.

Results:
Overall demographics and baseline characteristics were balanced between the erenumab 70 mg and placebo groups. At baseline, mean (±SD) age was 41.7 (±10.9) years, 81.5% (n=454) patients were women, and mean MMD was 19.21 (±5.41). The primary endpoint was met; patients in the erenumab 70 mg group had a significantly greater reduction in MMD from baseline compared to placebo. Moreover, patients in the erenumab 70 mg group had a significantly higher chance to achieve at least 50% reduction in MMD from baseline. Additionally, higher reductions in monthly acute headache medication days and mMIDAS scores were observed with erenumab 70 mg when compared to placebo. The safety and tolerability profile of erenumab 70 mg was overall similar to placebo, with the exception of constipation. Full study results will be presented during the congress.

Conclusions:
DRAGON study confirmed the efficacy and safety of erenumab 70 mg in adult patients with CM from China and other Asian countries. These results are consistent with previous pivotal studies.