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Efficacy and Safety of Erenumab in Patients with Episodic Migraine in Indian population: India sub-set analysis of Global EMPOwER study

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Objectives: EMPOwER (NCT03333109), a 12-week, double-blind, randomized study evaluated the efficacy and safety of erenumab (70 mg and 140 mg) in adult episodic migraine patients from Asia, the Middle East and Latin America. This is India sub-analysis of the Global study.

Methods: Indian Patients (N=351) were randomized to receive placebo, erenumab 70 mg or 140 mg (3:3:2). Primary endpoint was change from baseline in monthly migraine days (MMD). Secondary endpoints assessed ≥50% reduction in MMD, changes in headache impact test (HIT-6^{TM}) and safety.

Results: At baseline, mean (SD) age was 35.1 (± 8.6) years, 78.9 % were women; mean MMD was 7.82 (2.89). Change in MMD was numerically greater in erenumab groups (erenumab 70 mg and 140 mg) vs placebo (-4.65,-4.78 and -3.77; *p* vs placebo: 0.174 [70 mg] and 0.164 [140 mg]). Patients achieving ≥50% reduction in MMD was higher in erenumab 70 mg and 140 mg vs placebo (59.4% and 58.9% vs 50.8%; *p* vs placebo: 0.179 [70 mg] and 0.252 [140 mg]). Change in HIT-6^{TM} was -7.34 with placebo, -9.65 and -9.40 with erenumab 70 mg and 140 mg respectively (*p* vs placebo: 0.032 [70 mg] and 0.078 [140 mg]). Overall safety profile of erenumab was comparable

with placebo with no new safety signals.

Conclusion: While the study was not powered to evaluate the efficacy of erenumab in the Indian subpopulation, the efficacy and safety profile of erenumab in Indian patients showed improvement numerically for relevant endpoints versus placebo; thus consistent with the globalEMPOwER study population.