

LONG-TERM EFFECTIVENESS, SAFETY AND TOLERABILITY OF ATOGEPANT IN THE PREVENTION OF MIGRAINE: A MULTICENTRIC, PROSPECTIVE OBSERVATIONAL, REAL WORLD STUDY (THE 48-WEEK STAR STUDY)

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Background. To investigate the long-term effectiveness, safety and tolerability of atogepant for migraine prevention after 48 weeks of treatment.

Methods. At baseline (T0), weeks 9–12 (T3), 21–24 (T6) and 45-48 weeks (T12), monthly migraine days (MMDs), and main patients' reported outcomes were assessed. The co-primary outcomes were changes in MMDs and the percentage of MMDs ≥50% responders (50%RR) at T3, T6, and T12 compared to baseline. We also reported the proportion of patients achieving migraine freedom according to the International Headache Society proposal.

Results. Three hundred and seventy (370) patients from 17 Italian centers were enrolled (female 311, 84.1%, age 47.7 SD 0.7). Of these, 57 patients (15.4%) dropped out of treatment within the first 12 weeks; 85 (23.0%) within 24 weeks; and 118 (31.9%) within 48 weeks. Nineteen participants (16,1%) dropped out because of adverse events, 43 (36,4%) for inefficacy, 14 (11,9%) for both adverse events and inefficacy, and 42 (35,6%) for other reasons.In patients continuing therapy for 48 weeks, MMDs decreased from 16.5 (SD 0.5) to 7.8 (SD 0.5; p<0.001) at T3, 7.6 (SD 0.5) at T6, 7.9 (SD 0.5) at T12, while 50%RR was achieved in 52% of patients at T3, 48.1% at T6, and 43.3% at T12. At all evaluation times, patients affected by chronic migraine less frequently achieved 50%RR (p<0.01). Migraine freedom was achieved in 6.2% of patients at T3, 7.1%, at T6, and 8.4% at T12.Pain NRS reduced from baseline (8 IQR 1) to T3 (6 IQR 2, p<0.001) and remained stable until T12. The MIDAS scores almost halved from 64.9 at baseline (SD 47.8) to 23.9 (SD 32.1) at T12.Overall, patients' weight progressively decreased from baseline to T12 (p<0.001) and a clinically relevant (i.e.>7%) weight loss was observed in 43.9% of participants at T3, 47.2% at T6, and 50.0% at T12. No correlation was observed between clinical response and weight loss at all observation times.

Conclusions. The STAR study demonstrates the sustained effectiveness and tolerability of atogepant over 48 weeks. Discontinuations and weight loss support the need for long-term monitoring in clinical practice and treatment optimization.

On behalf of the Italian Headache Registry (RICe) Study Group.