during a migraine attack. **Methods:** RELIEF (NCT04152083; parallel-group, double-blind, placebo-controlled) randomized adults with migraine (4-15/d/mo in 3mo prior to screening) to eptinezumab 100mg or placebo, administered IV within 1-6h of qualifying migraine onset. Co-primary efficacy endpoints were time to headache pain freedom and time to absence of most bothersome symptom (MBS). **Results:** Eptinezumab (n=238) compared with placebo (n=242) achieved significantly faster headache pain freedom (median 4h vs 9h; hazard ratio=1.54, \( P=0.0006 \)) and absence of MBS (2h vs 3h; 1.75, \( P<0.0001 \)). At 2h, 23.5% and 12.0% (\( P=0.0009 \)) of eptinezumab-treated and placebo patients, respectively, reported headache pain freedom, and 55.5% and 35.8% (\( P<0.0001 \)) reported absence of MBS. Significantly fewer eptinezumab-treated patients used rescue medication within 24h (31.5% vs 59.9%; \( P<0.0001 \)). Treatment-emergent adverse events occurred in 10.9% eptinezumab-treated and 10.3% placebo patients; no serious adverse events occurred. **Conclusions:** Infusion of the preventive migraine treatment, eptinezumab, during a migraine resulted in rapid and sustained freedom from headache pain and MBS vs placebo, starting 2h post-infusion, decreasing need for acute medication within 24h post-infusion. No notable safety findings were identified.

**P.029**

**Oral Daily Atogepant for the Preventive Treatment of Migraine Increases Responder Rates for Reduction in Mean Monthly Migraine Days**

**Background:** The goal of the study was to assess responder rates at various times after initiating atogepant treatment. **Methods:** A 12-week phase 3 trial evaluated the safety, efficacy, and tolerability of atogepant for preventive treatment of migraine (ADVANCE; NCT03777059) in adult participants with a ≥1-year history of migraine, experiencing 4-14 migraine days/month. Participants were randomized to atogepant 10, 30, or 60mg, or placebo once daily. These analyses evaluated ≥25%, ≥50%, ≥75%, and 100% reductions in mean monthly migraine days (MMDs) across 12 weeks and each 4-week interval. Adverse events (AEs) in ≥5% of participants are reported. **Results:** The efficacy analysis population included 873 participants: placebo: n=214; atogepant: 10mg: n=214; 30mg: n=223; 60mg: n=222. Atogepant-treated participants were more likely to experience a ≥50% reduction in the 3-month mean MMDs (56-61% vs 29% with placebo; \( P<0.0001 \)). The proportions of participants experiencing ≥25%, ≥50%, ≥75%, and 100% reductions in mean MMDs significantly increased during each 4-week interval (≥50% reduction: 48-71% vs 27-47% with placebo). The most common AEs for atogepant were constipation (6.9-7.7%), and nausea (4.4-6.1%). **Conclusions:** Once-daily atogepant 10, 30, and 60mg significantly increased responder rates at all thresholds with approximately 60% achieving a ≥50% reduction in mean MMDs at 12 weeks.

**P.030**

**Long-term Safety and Tolerability of Atogepant 60 mg Following Once-Daily Dosing Over 1 Year for the Preventive Treatment of Migraine**

**Background:** The goal of the study was to assess the safety and tolerability of atogepant, an oral, calcitonin gene-related peptide receptor antagonist in development for migraine preventive treatment, once daily over 1 year. **Methods:** Multicenter, open-label trial (NCT03700320). Adults with migraine were randomized 5:2 to atogepant or oral standard-of-care (SOC) migraine prevention. **Results:** 744 randomized participants (n=546 atogepant), 739 safety population participants (n=543 atogepant). Adverse events (AEs) were reported by 67.0% of atogepant participants; 18.0% had AEs.