

migraine (CM) following eptinezumab treatment. Methods: PROMISE-2 (NCT02974153) was a double-blind, placebo-controlled, parallel-group trial that randomized adults with CM to eptinezumab 100 mg, 300 mg, or placebo IV every 12 weeks for up to 24 weeks (2 infusions). Headache episodes (migraine and non-migraine) and their characteristics were reported in daily electronic diaries during the 28-day baseline period and throughout the 24-week treatment period. Results: A total of 1072 patients were included. Patients reported a mean of 20.4–20.6 monthly headache days during baseline across treatment groups. Mean monthly headache days decreased by 8.9 (100 mg) and 9.7 (300 mg) with eptinezumab versus 7.3 with placebo over weeks 1–24. Mean monthly headache episodes also decreased by 8.4 (100 mg) and 9.0 (300 mg) compared to 7.1 with placebo over weeks 1–24. Among headaches occurring post-treatment, decreases in severe pain, nausea, phonophobia, photophobia, and physical activity limitations were numerically greater than placebo. Conclusions: In patients with CM, eptinezumab numerically decreased the frequency and severity of monthly headache days and episodes more than placebo. Patients treated with eptinezumab reported a decrease in burdensome symptoms of headache episodes.

P.017

Optimization of acute treatment and headache-related impact following eptinezumab initiated during a migraine attack: post hoc analysis of the RELIEF study

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Background: Patients administered eptinezumab during an active migraine had larger numerical improvement in the 6-item Migraine Treatment Optimization Questionnaire (mTOQ-6) total score compared to placebo. The mTOQ-6 was used to determine success of acute treatment. Methods: RELIEF (NCT04152083) was a double-blind trial that randomized adults eligible for preventive migraine treatment to eptinezumab 100mg or placebo, administered intravenously within 1–6 hours of migraine onset. mTOQ-6 was captured at baseline and Week 4 and rescored into mTOQ-4. Patients were grouped by baseline mTOQ-4 total scores. Results: 226 eptinezumab-treated and 232 placebo patients were included. The percentage of patients in the combined very poor and poor optimization subgroups at baseline with eptinezumab (n=155; 68.6%) versus placebo (n=138; 59.5%) decreased by 26.6 percentage points (n=95; 42.0%) and 9.9 percentage points (n=115; 49.6%), respectively, at Week 4. Of the 155 eptinezumab-treated and 138 placebo patients who were very poorly/poorly optimized at baseline, 73 (47.1%) versus 35 (25.4%) were moderately/maximally optimized at Week 4, respectively. Greater improvements in mTOQ-6 scores were noted in patients more poorly optimized at baseline than those more optimized. Conclusions: Eptinezumab showed greater acute migraine medication optimization and decreased headache-related impact compared to placebo, suggesting that eptinezumab may work synergistically with acute medications.

P.018

Treatment patterns and healthcare resource utilization for patients with migraine in Alberta

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Background: As the second leading cause of years lived with disability in the world, and the first in people under 50, migraine represents a major burden to healthcare systems. This study examined treatment patterns and healthcare resource utilization (HRU) in patients with migraine using real-world data from Alberta. Methods: This was a retrospective cohort study of patients with ≥1 ICD-9-CM/ICD-10-CA code for migraine or ≥1 prescription for a triptan from April 1st, 2012 to March 31st, 2018. Descriptive statistics were used to characterize the study outcomes. Results: The incidence of migraine exceeded 1,000 cases per 100,000 person-years over the study period. The mean age of the cohort (n=199,931) was 40.0, and 72.3% were women. Migraine-related HRU accounted for 3%–10% of all HRU across endpoints (e.g., ED visits, hospitalization, physician visits). One-third of the cohort were prescribed acute medications (non-steroidal anti-inflammatories, triptans or other (including opioids)), whereas fewer than one-fifth were prescribed at least one migraine preventive such as tricyclic anti-depressants (proportion: 15%), anti-convulsants (13%), beta-blockers (7%), or neurotoxins (4%). Conclusions: The low medication prescription rates and high HRU indicates the potential unmet need and high disability in patients with migraine. The impact of migraine treatment patterns on HRU is an avenue for future research.

P.019

Interictal burden of migraine: correlations with other measures of migraine burden and effects of galcanezumab migraine-preventive treatment

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Background: Typical migraine clinical trial endpoints assess only ictal burden. Methods: Adults (N=462) with episodic or chronic migraine with previous failure of 2–4 preventive medication categories were randomized 1:1 to 3-month double-blind treatment with placebo or galcanezumab 120mg. Primary endpoint was mean change from baseline in monthly migraine headache days. Migraine Interictal Burden Scale-4 (MIBS-4) measured migraine-related burden on non-headache days for past 4 weeks (0=no burden, 1–2=mild, 3–4=moderate, 5–12=severe). Migraine Disability Assessment (MIDAS), Migraine-Specific Quality of Life Questionnaire (MSQ), Patient Global Impression-Severity (PGI-S), depression (Patient Health Questionnaire-9 [PHQ-9]), and anxiety (Generalized Anxiety Disorder Scale [GAD-7]) were assessed. Relationships among measures were assessed at baseline using Spearman's rank correlation coefficient. Results: MIBS-4 was moderately correlated with

PHQ-9 ($r=.55$) and MSQ total ($r=.53$). Other correlations with MIBS-4 were low (GAD-7, $r=0.42$; MIDAS, $r=0.41$; PGI-S, $r=0.32$) or negligible (migraine headache days, $r=0.22$). After 3 months, from a mean baseline of 13.2 monthly migraine headache days, galcanezumab patients improved by 4.4 vs 1.3 days for placebo ($p<.0001$). From mean MIBS-4 baseline of 5.5, galcanezumab patients improved by 1.8 vs 0.8 points for placebo ($p<.0001$). Conclusions: Galcanezumab significantly reduced ictal and interictal burden of migraine. Results suggest interictal burden is a distinct effect of the disease.

P.020

Long-term safety and tolerability of atogepant 60mg once daily for preventive treatment of migraine: a phase 3, 40-week, multicenter extension to the advance trial

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Background: A phase 3 trial, ADVANCE (NCT03777059), demonstrated that atogepant, an oral, CGRP receptor antagonist dosed once daily, results in clinically meaningful reductions in mean monthly migraine days. This open-label extension for ADVANCE trial completers evaluated long-term safety and tolerability of atogepant over 40-weeks. Methods: Participants in this trial (NCT03939312), rolled over from the ADVANCE trial, were treated with atogepant 60mg once daily for 40-weeks, with a 4-week safety follow-up. Only safety data were collected. Results: 685 participants took at least one dose of study drug, 74.6% completed the 40-week treatment period; mean age of 41.8 years, 88.2% female, 84.4% white, and mean BMI of 30.58 kg/m². Mean (SD) treatment duration was 233.6 (89.32) days. 62.5% of participants experienced a treatment-emergent adverse event (TEAE), with 8.8% considered treatment-related by the investigator; serious adverse events (SAEs) occurred in 3.4% of participants, none were treatment-related. The most frequent AEs leading to discontinuation was nausea (0.4%, $n=3$); the most frequent TEAEs observed included upper respiratory tract infection (5.5%, $n=38$) and urinary tract infection (5.3%, $n=36$). No deaths or hepatic safety issues were observed. Conclusions: Safety results are consistent with known safety profile of atogepant and support long-term safety and tolerability of once daily dosing of atogepant 60mg.

P.021

Evaluation of PREEMPT fixed-dose, fixed-site and follow the pain treatment paradigms in the PREDICT Study

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Background: Phase 3 PREEMPT established safety and efficacy of 155-195U onabotulinumtoxinA in adults with chronic

migraine (CM). This analysis of the PREDICT study (NCT02502123) evaluates real-world effectiveness and safety of 155U, 156-195U and 195U-onabotulinumtoxinA in CM. Methods: Patients received onabotulinumtoxinA approximately every 12-weeks (≤ 7 treatment cycles [Tx]) per Canadian product monograph). Primary endpoint was mean change from baseline in Migraine-Specific Quality of Life (MSQ) at Tx4. Headache days, physician and patient satisfaction were evaluated. Analysis stratified safety population (≥ 1 onabotulinumtoxin A dose) into 3 groups (155U, 156-195U, 195U) by dose received on ≥ 3 of the first 4 Tx. Results: 184 patients received ≥ 1 onabotulinumtoxin A dose (155U, $n=68$; 156-195U, $n=156$; 195U, $n=13$ on ≥ 3 Tx). Headache days decreased over time compared to baseline (Tx4: -7.1[6.7] 155U; -6.5[6.7] 156-195U; -11.2[6.4] 195U). Physicians rated most patients as improved, and majority of patients were satisfied at final visit (80.8% 155U; 83.6% 156-195U; 90% 195U). Treatment-emergent adverse events (TEAEs) were reported in 18/68(26.5%) patients in 155U-group, 41/65(63.1%) in 156-195U-group and 10/13(76.9%) in 195U-group; treatment-related TEAEs were 9(13.2%), 10(15.4%) and 3(23.1%) respectively; serious TEAEs were 0, 3(4.6%) and 1(7.7%), none treatment-related. Conclusions: Long-term treatment with 155U, 156-195U, and 195U-onabotulinumtoxinA in PREDICT was safe and effective CM treatment. No new safety signals were identified.

MOVEMENT DISORDERS

P.022

Prognosis in arm and leg tremor onset Parkinson Disease

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Background: There is no biological marker of progression in early Parkinson Disease (PD). Upper limb (UL) tremor is the most common motor symptom at onset. The significance of lower limb (LL) tremor remains unknown. We report on longitudinally followed autopsy-verified PD tremor onset cases. Methods: A chart review of longitudinally followed autopsy-verified PD cases was performed. Age and mode of onset were recorded at initial evaluation. Prognosis was measured by change in Hoehn and Yahr scale while on levodopa (LD). Results: Forty-nine patients were included. Thirty-eight cases had upper limb (UL), four lower limb (LL), and seven upper and lower limb (ULL) onset tremor. UL had 86.8% response to LD, LL 50% and ULL 85.7%. Sub-analysis of UL responders found 20% mild improvement, 53.3% moderate and 26.7% marked. ULL had moderate response in 83.3% and marked in 16.7%. LL responders only had mild improvement with LD. Conclusions: Tremor onset is most common in UL, followed by ULL and then LL. LL onset tremor cases have an inferior response to LD when compared to UL and ULL cases. We plan for further pathophysiologic studies to investigate LL onset in PD.