

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

B Klein (Abington) *R Miceli* (Madison) *L Severt* (Madison) *P McAllister* (Stamford) *L Mechtler* (Amherst) *J McVige* (Amherst) *M Diamond* (Chicago) *MJ Marmura* (Philadelphia) *E Leroux* (Montreal)* *H Guo* (Madison) *M Finnegan* (Madison), *J Trugman* (Madison)

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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

C Graboski (Brentwood Bay) *M Ong-Lam* (Vancouver) *W Becker* (Calgary) *G Boudreau* (Montreal) *G Davidovic* (Toronto) * *J Ma* (Madison) *K Sommer* (Irvine), *I Finkelstein* (Toronto)

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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

E Noyes (Saskatoon)* *A Rajput* (Saskatoon), *A Rajput* (Saskatoon)

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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.