EPO-0246 | Effect of Atogepant on cognitive function following acute treatment of migraine across multiple attacks: Results from the ECLIPSE trial

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Background and aims: Atogepant is approved for the preventive treatment of migraine in adults and has recently demonstrated its efficacy and safety for the acute treatment of migraine. This analysis evaluated the impact of atogepant 60mg administered as needed (PRN) for acute treatment of migraine on cognitive function assessed by the ability to think clearly.

Methods: ECLIPSE was a double-blind (DB), placebo-controlled, multiple-attack, crossover trial evaluating atogepant's efficacy, safety, and tolerability for acute migraine treatment. Adults with 2–8 monthly moderate-to-severe attacks were randomised to receive atogepant for three qualifying attacks and placebo for one attack during the up to 16-week DB period. Cognitive function scale is a single-item, patient-reported questionnaire measuring participants' difficulty in ability to think clearly, rated from 0 (not difficult at all) to 3 (very difficult). The proportion of participants achieving the ability to think clearly at 2-, 4-, and 8-hours postdose across attacks 1–4 was an additional (exploratory) efficacy endpoint. Data for atogepant and placebo are presented with nominal *p*-values.

Results: Atogepant treatment resulted in a nominally significant higher proportion of participants achieving the ability to think clearly compared with placebo as early as 2-hours postdose in the first treated attack (OR: 1.78, Figure 1); this effect increased over time through 4- and 8-hours postdose (OR: 3.39, 3.73, respectively; Figure 1). A similar reliable response was observed across attacks 2–4 (Figure 2).

Conclusion: A greater proportion of participants treated with atogepant achieved the ability to think clearly compared to placebo as early as 2-hours and up to 8-hours postdose across multiple attacks.

Disclosure: AVD has served on advisory/scientific boards and/or given lectures for AbbVie/Allergan, Angelini Pharma, Eli Lilly, Lundbeck, Neuraxpharm, Novartis, Organon, Pfizer, TEVA, and UCB, for which she has received honoraria. RO reports personal fees from AbbVie, Bayer, Eli Lilly, Lundbeck, Novartis, Organon, Pfizer, and Teva. He is a member of the Editorial Board of The Journal of Headache and Pain, International Journal of Stroke, Arquivos de Neuropsiquiatria, and Confinia Cephalalgica. RG-G has received honoraria for consultant and/or advisory boards from Allergan/Abbvie, Astra Zeneca, Almirall, Bial, Biogen, Bristol-Myers Squibb, CMBE, FLOAT, Lilly, Lundbeck, Merk, Novartis, Novo Nordisk, Organon, Pfizer, Roche, Sanofi, Tecnifar and Teva; research funding from Fundação Ciência Tecnologia (Project 29675, MigN2Treat, 02/SAICT/2017); Learning-Health, Luz Saúde (LiON, Luz Innovation on Neurosciences); Novartis-Sociedade Portuguesa de Cefaleias; Bolsa –Projecto Centro de Investigação Interdisciplinar em Saúde and UCP. PPR reports personal fees for consulting from AbbVie, Amgen, Dr. Reddy's, Eli Lilly, Lundbeck, Medscape, Novartis, Organon, Pfizer, and Teva in the last three years. She has received personal fees for speaking from AbbVie, Amgen, Dr. Reddy's, Eli Lilly, Lundbeck, Medscape, Novartis, Organon, Pfizer and Teva, and has had grants paid to her research group from AbbVie, AGAUR, EraNet Neuron, FEDER

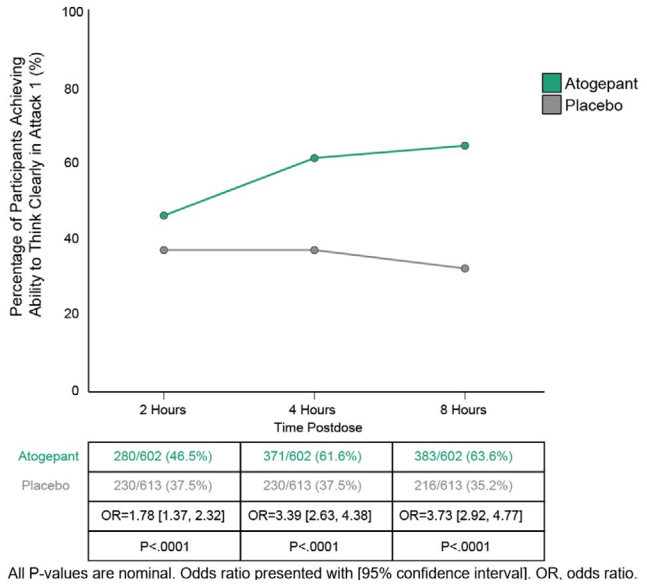

FIGURE 1: Proportion of participants who reported "not difficult at all" in ability to think clearly at 2-, 4-, and 8-hours postdose in the first migraine attack.

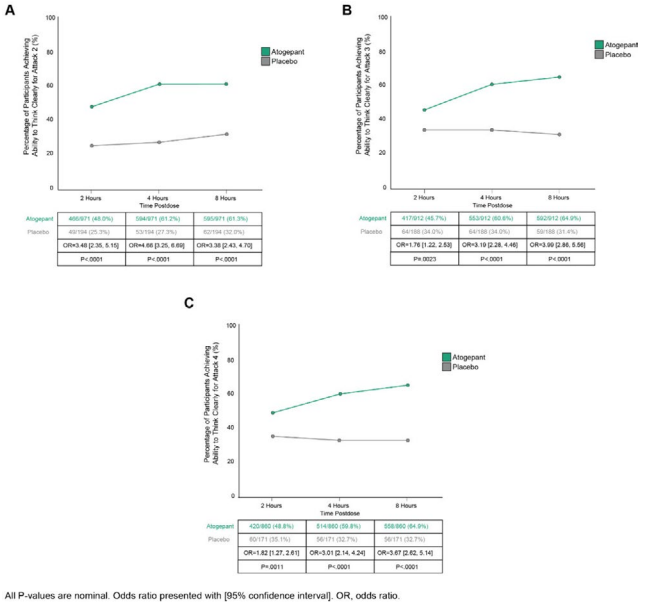

FIGURE 2: Proportion of participants who reported "not difficult at all" in ability to think clearly at 2-, 4-, and 8-hours postdose across attacks 2, 3, and 4 (A, B, and C, respectively).

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RIS3CAT, Instituto Investigación Carlos III, Novartis, and Teva. UR has served on advisory boards for AbbVie, Eli Lilly, Lundbeck, Novartis, Pfizer, and Teva and has received institutional honoraria for lectures from AbbVie, Eli Lilly, Lundbeck, Novartis, StreaMedUp, Springer, and Teva, received institutional honoraria for consulting services from Lundbeck, Pfizer, and AbbVie; received research funding from Novartis (CHERUB01) and the German Federal Ministry of Education and Research; UR is an associate editor of the Journal of Headache and Pain, and is the president of the EHF. GA, EB-S, LL, CC, and KC are employees of AbbVie and may hold AbbVie stock.

EPO-0247 | Longitudinal shifts in migraine frequency patterns: Transition from chronic to episodic migraine in a pooled analysis of the PEARL and FINESSE studies

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Background and aims: Chronic migraine (CM) is associated with increased disability, greater reductions in health-related quality of life and higher rates of medication overuse compared with episodic migraine (EM). Consequently, achieving reversion from CM to EM is an important therapeutic goal. This analysis assessed long-term changes in migraine frequency among participants with CM in PEARL and FINESSE.

Methods: The 24-month, prospective, observational, real-world PEARL (pan-European) and FINESSE (Germany and Austria) studies evaluated the effectiveness and tolerability of fremanezumab in routine clinical practice among adults with migraine. Mean monthly migraine days (MMD) were assessed using daily headache diaries completed by participants throughout the study. In this pooled analysis, the proportions of participants shifting from CM (diagnosed at baseline) to high-frequency EM (HFEM; > =8 and <15 MMD), moderate-frequency EM (MFEM; > =4 and <8 MMD) and low-frequency EM (LFEM; <4 MMD) were assessed over time.

Results: Of 2145 participants included in the pooled analysis, 1212 had CM at baseline (Table 1). By Month 6, 20.4%, 25.0% and 39.5% of participants with available data ($n=1070$) had transitioned to HFEM, MFEM and LFEM, respectively (Table 2). At Month 24, 49.5% of participants with available data ($n=641$) had shifted to LFEM and only 7.6% of participants still had >15 MMD.

TABLE 1 Baseline characteristics.

	Participants in the PEARL & FINESSE studies N=2145
Age	
Mean (SD)	45.96 (12.17)
Median (Min, Max)	47 (18, 85)
Past preventive migraine treatment attempts, n (%)	
<4	1397 (65.1)
>=4	748 (34.9)
Time from initial migraine onset date to fremanezumab initiation, years	
Mean (SD)	26.72 (13.53)
Median (Min, Max)	26 (0, 70)
Time from date of migraine diagnosis to first fremanezumab initiation, years	
Mean (SD)	16.12 (12.79)
Median (Min, Max)	13 (0, 65)
Presence of onabotulinumtoxinA failure as a past preventive treatment, n (%)	781 (36.4)
Migraine diagnosis, n (%)	
CM	1212 (56.5)
EM	933 (43.5)

CM, chronic migraine; EM, episodic migraine; Max, maximum; Min, minimum; SD, standard deviation.

TABLE 2 Proportion of participants transitioning from CM at baseline to HFEM, MFEM and LFEM at Months 6, 12, 18 and 24.

	Month 6		Month 12		Month 18		Month 24	
	Participants with data available (n=1070)	Participants who discontinued prematurely or had missing data n (%)	Participants with data available (n=927)	Participants who discontinued prematurely or had missing data n (%)	Participants with data available (n=819)	Participants who discontinued prematurely or had missing data n (%)	Participants with data available (n=641)	Participants who discontinued prematurely or had missing data n (%)
Without improvement, n (%)	161 (15.0)	142 (11.7)	110 (11.9)	285 (23.5)	89 (10.9)	393 (32.4)	49 (7.6)	571 (47.1)
Shifted to HFEM, n (%)	218 (20.4)		201 (21.7)		168 (20.5)		113 (17.6)	
Shifted to MFEM, n (%)	268 (25.0)		243 (26.2)		188 (23.0)		162 (25.3)	
Shifted to LFEM, n (%)	423 (39.5)		373 (40.2)		374 (45.7)		317 (49.5)	

At baseline, 1212 participants in the pooled analysis had been diagnosed with CM. The drop in data at post-baseline timepoints is due to participants who prematurely discontinued the studies and participants with missing data. Missing data were excluded.
Reasons for study discontinuation among participants with CM at Month 24 were as follows: fremanezumab treatment discontinued and new prophylactic treatment for migraine medication prescribed (n=89); lost to follow-up (n=80); withdrawal by participant (n=76); withdrawal due to adverse events (n=57); non-compliance with study procedures (n=17); other reasons including lack of efficacy/treatment interruption/patient decision/child wish/clinical improvement/treatment continuation by another clinic or another physician/pregnancy (n=115); and death (n=2). Cause of death was pancreatic cancer for one participant and COVID-19 for one participant; both deaths were considered 'not related to fremanezumab' by the treating physicians. At Month 24, missing data were reported for 133 participants.
Without improvement: >15 MMD; HFEM: >=8 and <15 MMD; MFEM: >=4 and <8 MMD; LFEM: <4 MMD.
CM, chronic migraine; HFEM, high-frequency episodic migraine; LFEM, low-frequency episodic migraine; MFEM, moderate-frequency episodic migraine; MMD, monthly migraine days.

Conclusion: Fremanezumab facilitated meaningful reductions in migraine frequency over time, with nearly half of the participants with CM who persisted with treatment up to Month 24 transitioning to LFEM. These findings highlight the long-term benefit of fremanezumab and its potential to restore low disease burden in a relevant subset of patients.

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