Impact of Atogepant on Activity Limitation in Participants With Episodic Migraine and Chronic Migraine: Post Hoc Analyses of ADVANCE, ELEVATE and PROGRESS

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OBJECTIVE

To evaluate the proportion of atogepant-treated participants reporting no limitations in activity using a daily diary measure for Weeks 1, 2, 3, and 4 across three phase 3 trials compared with placebo-treated participants

CONCLUSIONS

As early as Week 1 after starting atogepant treatment, a greater proportion of participants reported "they could do everything" in all three trials compared with placebo-treated participants; consistent results were seen at Weeks 2, 3, and 4

Atogepant-treated participants were more likely to report "they could do everything" compared with placebo-treated participants at Week 1 and consistent effects were seen at Weeks 2, 3, and 4

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INTRODUCTION

- Atogepant is an oral calcitonin gene-related peptide receptor antagonist approved for the preventive treatment of migraine in the US and EU[1,2]
- ADVANCE, ELEVATE, and PROGRESS were phase 3, multicenter, randomized, double-blind, placebo-controlled, 12-week trials[3,4,5]
  - The trials included adults with episodic migraine (EM), EM with prior inadequate responses to 2-4 conventional oral preventive treatments, and chronic migraine (CM), respectively
  - These analyses report placebo and atogepant 60 mg once daily (QD), the only dose common between all 3 trials
- This post hoc analysis compared the proportion of participants who reported no limitations in activity when treated with atogepant versus placebo at Weeks 1, 2, 3, and 4 across three phase 3 clinical trials

Table 1: Phase 3 Trial Cohort Demographics

	ADVANCE (EM)		ELEVATE (EM + Prior Inadequate Response to Treatment)		PROGRESS (CM)	
	Placebo (N = 222)	Atogepant 60 mg QD (N = 231)	Placebo (N = 157)	Atogepant 60 mg QD (N = 156)	Placebo (N = 255)	Atogepant 60 mg QD (N = 281)
Age, years, mean (SD)	40.3 (12.8)	42.5 (12.4)	43.4 (10.3)	40.9 (10.7)	42.0 (12.4)	41.7 (12.3)
Sex, female, N (%)	198 (89.2)	199 (86.1)	141 (89.8)	139 (89.1)	255 (88.2)	225 (86.2)
Race, N (%)						
Caucasian	194 (87.4)	192 (83.1)	151 (96.2)	149 (95.5)	151 (59.2)	157 (60.2)
Black or African American	24 (10.8)	28 (12.1)	4 (2.5)	3 (1.9)	7 (2.7)	9 (3.4)
Asian	2 (0.9)	7 (3.0)	2 (1.3)	2 (1.3)	94 (36.9)	92 (35.2)
American Indian or Alaskan Native	0	1 (0.4)	0	0	1 (0.4)	1 (0.4)
Native Hawaiian or Other Pacific Islander	0	0	0	0	1 (0.4)	0
Multiple	2 (0.9)	2 (0.9)	0	2 (1.3)	1 (0.4)	2 (0.8)
Region, N (%)						
North America	222 (100)	231 (100)	20 (12.7)	20 (12.8)	75 (29.4)	79 (30.3)
Europe	0	0	137 (87.3)	136 (87.2)	89 (34.9)	91 (34.9)
East Asia	0	0	0	0	91 (35.7)	91 (34.9)

CM, chronic migraine; EM, episodic migraine; N, number of participants; QD, once daily; SD, standard deviation.

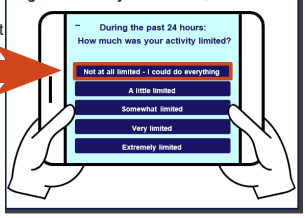
METHODS

- Activity limitation was quantified by a single-item questionnaire with 5-level response scale (**Figure 1**)
  The answers were based off a 24-hour recall
- To report no limitations in activity, a participant would select

"Not at all limited - I can do everything"

- Baseline activity was at least "A little limited" for all participants
  --Baseline period was 1 week prior to randomization
- The post hoc analyses compared the proportions of placebo and atogepant-treated participants who reported no limitations in activity for all available days within a week

Figure 1: Activity Limitation Questionnaire



Study Population

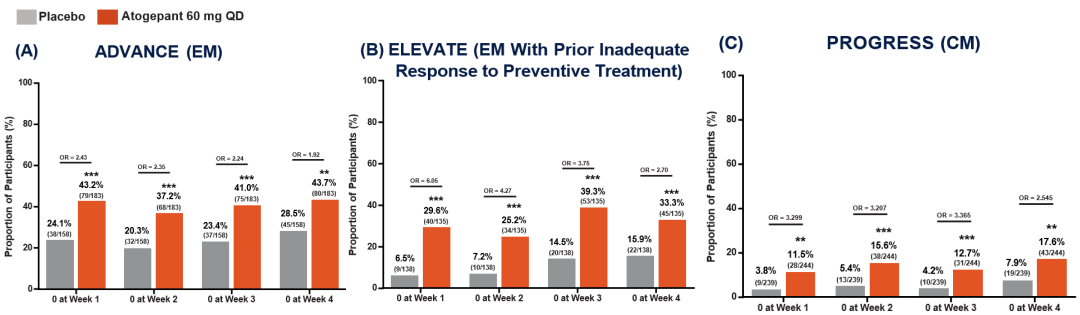
- Participants are from the modified intent-to-treat populations of ADVANCE, ELEVATE, and PROGRESS (**Table 1**)

Statistical Analysis

- Fisher's exact test was used to compare the proportion of atogepant and placebo patients responding no limitations in activity at each week
  - All *P* values reported are nominal as post hoc analyses are not controlled for multiplicity
- Odds ratios were calculated at each time point

RESULTS

Figure 2: Greater Proportions of Atogepant Treated Participants Reported No Limitations in Activity (i.e. They Could Do Everything) Compared With Placebo at Weeks 1, 2, 3, and 4 Among Participants Who Reported at Least a Little Activity Limitation at Baseline



** $P \leq .01$, *** $P \leq .001$, P values are nominal. P values for OR are as follows; Week 1 P < .001, Week 2 P < .001, Week 3 P < .001, Week 4 P = .005. Parentheses indicate (n/N1) of participants at each time point. Baseline activity limitation mean (SD): placebo 0.92 (0.654) N = 158; atogepant 0.84 (0.586) N = 183. EM, episodic migraine; n, number of responders; N, number of participants; N1, number of responders with evaluable data at a specific time point; OR, odds ratio; QD, once daily.

*** $P \leq .001$, *P* values are nominal. *P* values for OR are as follows; Week 1 *P* < .001, Week 2 *P* < .001, Week 3 *P* < .001, Week 4 *P* < .001.
Parentheses indicate (n/N1) of participants at each time point. Baseline activity limitation mean (SD): placebo 0.97 (0.645) N = 138; atogepant 0.85 (0.561) N = 135. EM, episodic migraine; n, number of responders; N, number of participants; N1, number of responders with evaluable data at a specific time point;OR, odds ratio; QD, once daily.

** $P \leq .01$, *** $P \leq .001$, *P* values are nominal. *P* values for OR are as follows; Week 1 *P* = .002, Week 2 *P* < .001, Week 3 *P* = .001, Week 4 *P* = .001. Parentheses indicate (n/N1) of participants at each time point. Baseline activity limitation mean (SD): placebo 1.47 (0.747) N = 239; atogepant 1.48 (0.791) N = 244. CM, chronic migraine; n, number of responders; N, number of participants; N1, number of responders with evaluable data at a specific time point; OR, odds ratio; QD, once daily.

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