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Consistency of Response to Rimegepant for the Acute Treatment of Migraine: A Population and Participant-Level Analysis of a Prospective Real-World Observational Study (CONFIDENCE)

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BACKGROUND

- Rimegepant is an oral calcitonin gene-related peptide (CGRP) receptor antagonist approved for the acute treatment of migraine and the preventive treatment of episodic migraine in many countries.[1,2]
  - The ability of rimegepant to reduce the acute symptoms of migraine has been demonstrated in 5 phase 2/3 trials.[3-7]
- Despite utilizing preventive therapy, many people living with migraine experience breakthrough attacks.[8]
  - There are limited data evaluating the use of rimegepant for the acute treatment of migraine over multiple attacks in the real world, particularly in the context of preventive therapy.
- The prospective, observational CONFIDENCE study (NCT06467370) evaluated the effectiveness of rimegepant for the acute treatment of migraine over multiple attacks, including in participants using preventive therapy.
- The interim analyses from CONFIDENCE comprised data from 142 participants with ≥1 rimegepant-treated migraine attack and 706 rimegepant-treated attacks.
  - Across all 706 rimegepant-treated attacks, 58.6% achieved meaningful pain relief within 2 h of treatment and 56.4% achieved a meaningful improvement in function within 2 h of treatment.[9]
  - Across the 118 participants with ≥3 rimegepant-treated migraine attacks, 62.7% achieved meaningful pain relief within 2 h in ≥2 of their first 3 rimegepant-treated attacks, and 60.2% achieved meaningful improvement in function within 2 h of treatment in ≥2 of their first 3 rimegepant-treated attacks.[10]
- The CONFIDENCE study is now complete, and the current analysis explores the consistency of response to rimegepant at the population (all attacks) and participant level using the full dataset.

METHODS

STUDY DESIGN

- The CONFIDENCE study was carried out through a custom interface of the Migraine Buddy® app, which is a widely used tool for tracking migraine attack symptoms, triggers, and treatment outcomes.[11]
- The study comprised a baseline questionnaire, daily diary for 28 days, and study completion questionnaire.
- The daily diary assessed the occurrence and nature of any migraine attacks, any acute treatments taken, the effectiveness of treatment (pain relief and function), and satisfaction with treatment.

PARTICIPANTS

- Participants were recruited from existing Migraine Buddy users in the United States.
- Key enrollment criteria:
  - Age ≥18 years.
  - 3–14 headache days in the last 30 days.
  - Prior rimegepant prescription for the acute treatment of migraine and plan to use rimegepant to treat a migraine attack during the next 30 days.
  - Not using rimegepant as preventive treatment.
  - Stable use of other indicated preventive treatment was permitted except concomitant use of onabotulinumtoxinA with any anti-CGRP monoclonal antibody.
  - No diagnoses of cluster headache, post-traumatic headache, new daily persistent headache, hemicrania continua, or secondary headache disorders.

ANALYSES

- Analyses evaluated the incidence of positive treatment outcomes in rimegepant-treated migraine attacks reported in the study, including:
  - Meaningful pain relief, as reported by the participant, within 2 h of treatment.
  - Meaningful improvement in function, as determined by the participant, within 2 h of treatment.
  - Participant reported being "satisfied" or "extremely satisfied" (on a 7-point scale) with rimegepant treatment of the attack.
- Analyses were conducted at 2 levels:
  - Population: % Rimegepant-treated attacks where each positive treatment outcome was achieved.
  - Participant: % Participants who achieved each positive treatment outcome in ≥2 of their first 3 rimegepant-treated attacks reported in the study.

RESULTS

- Overall, 416 of the 429 enrolled participants reported ≥1 rimegepant-treated migraine attack.
- The 416 participants were a mean (SD) age of 39.6 (10.9) years, 86.1% were female, and 90.4% were White (**Table 1**).
  - Median headache days in the past 30 days: 8 (IQR, 5–10).
  - 89.9% had moderate to severe disability per their Migraine Disability Assessment Score (MIDAS).

CONSISTENCY AT THE POPULATION LEVEL

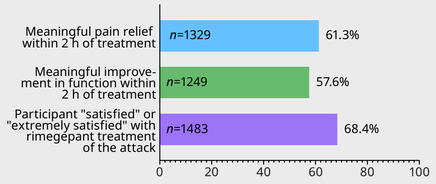
- Of the 3274 recorded migraine attacks, 2169 (66.2%) were treated with rimegepant.
- Among the 2169 rimegepant-treated attacks (**Figure 1**):
  - 61.3% achieved a meaningful pain relief within 2 h of treatment.
  - 57.6% achieved a meaningful improvement in function within 2 h of treatment.
  - 68.4% of participants reported being "satisfied" or "extremely satisfied" with rimegepant treatment of the attack.

Table 1: Demographics and clinical characteristics

Demographic	Participants with ≥1 rimegepant-treatment migraine attack *N*=416
Age, mean (SD), y	39.6 (10.9)
Female gender, *n* (%)	358 (86.1)
White race, *n* (%)	376 (90.4)
BMI, mean (SD), kg/m^2	30.0 (7.6)
Headache days/month, median (IQR)	8 (5–10)
MIDAS classification, *n* (%)	
None to mild disability (score 0–10)	42 (10.1)
Moderate to severe disability (score ≥11)	374 (89.9)
Use of indicated migraine preventive therapy, *n* (%)[a]	
Any	350 (84.1)
CGRP mAb	141 (33.9)
OnabotulinumtoxinA	140 (33.7)
Anticonvulsant	41 (9.9)
Antidepressant	40 (9.6)
Atogepant	40 (9.6)
Beta-blocker	28 (6.7)
Angiotensin blocker	1 (0.2)
Calcium channel blocker	3 (0.7)

[a] Participants could use >1 type of preventive medication.
BMI=body mass index; CGRP=calcitonin gene-related peptide; IQR=interquartile range; mAb=monoclonal antibody; MIDAS=Migraine Disability Assessment Score

Figure 1: Outcomes in all rimegepant-treated migraine attacks



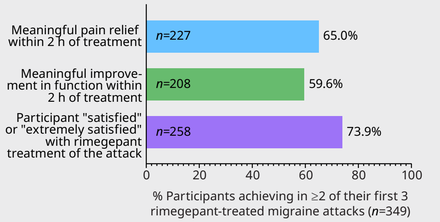
CONCLUSIONS

- Consistently positive treatment outcomes were observed at the population (all attacks) and participant levels in this real-world observational study of >400 participants and >2000 migraine attacks where rimegepant was used for the acute treatment of migraine.
- 61%, 58%, and 68% of rimegepant-treated migraine attacks achieved a meaningful reduction in pain within 2 h, meaningful improvement in function within 2 h, and overall treatment satisfaction, respectively.
  - 65%, 60%, and 74% of participants achieved each of these positive outcomes in ≥2 of their first 3 rimegepant-treated attacks.
- The majority of participants were taking stable preventive therapy, demonstrating the benefit of rimegepant in the treatment of breakthrough migraine attacks.

CONSISTENCY AT THE PARTICIPANT LEVEL

- 349 participants reported ≥3 rimegepant-treated migraine attacks.
- Among these 349 participants (**Figure 2**):
  - 65.0% achieved meaningful pain relief within 2 h of treatment in ≥2 of their first 3 attacks.
  - 59.6% achieved a meaningful improvement in function within 2 h of treatment in ≥2 of their first 3 attacks.
  - 73.9% reported being "satisfied" or "extremely satisfied" with rimegepant treatment in ≥2 of their first 3 attacks.

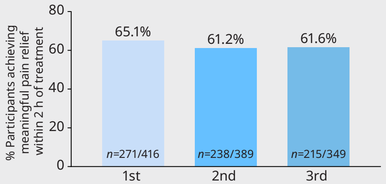
Figure 2: Outcomes achieved in ≥2 of each participant's first 3 rimegepant-treated migraine attacks



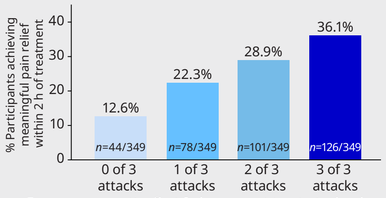
- Specifically, 65.1% of participants achieved meaningful pain relief within 2 h of rimegepant treatment in their first recorded attack, 61.2% in the second, and 61.6% in the third (**Figure 3A**).
- Further, 36.1% of participants achieved meaningful pain relief within 2 h of rimegepant treatment in all of their first 3 recorded attacks: 28.9% in 2 of 3, 22.3% in 1 of 3, and 12.6% in none (**Figure 3B**).

Figure 3: Meaningful pain relief in each participant's first 3 rimegepant-treated migraine attacks

A. % Achieving meaningful pain relief within 2 h of rimegepant treatment in each attack



B. Frequency of meaningful pain relief achievement within 2 h of rimegepant treatment



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DISCLOSURES

AU: Employee of Aptar Digital Health, which was a paid consultant to Pfizer for the conduct of this study. **GL:** Speaker honoraria, funding for travel, and honoraria for participation in advisory boards: AbbVie, Dr Reddy's Laboratories, Eli Lilly, Lundbeck, Novartis, Pfizer, and Teva. **RBL:** Editorial board of Neurology and senior advisor to Headache (not paid roles); research support: NIH and FDA; support from the National Headache Foundation; research grants, consultant, advisory board, or honoraria: Allergan/AbbVie, Amgen, Axsome, Dr Reddy's Laboratories, Eli Lilly, GlaxoSmithKline, Ipsen, Lundbeck, Pfizer, Merck, Teva, Vedanta; royalties: Informa and Wolff's Headache (8th edition, Oxford University Press, 2009); stock options: Biohaven Pharmaceuticals, CoolTech, Manistee, NuVelloBio, PJSG. Consulting fees: Aeon, AbbVie, CoolTech, Dr Reddy's Laboratories, Eli Lilly, Epalex, Ipsen, Kallyope, Linpharma, Lundbeck, Orion Pharma, Pfizer, PureTech Health, Satsuma, Seaport Therapeutics, Shiratronics, Teva; personal fees for advice: Gerson Lehrman Group, Guidepoint, SAI Med Partners, Vector Psychometric; fees for educational materials: CME Outfitters and WebMD; publishing royalties or fees: Massachusetts Medical Society, Oxford University Press, UptoDate, and Wolters Kluwer.

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