Consistency of Response to Rimegepant: A Patient-Level Interim Analysis of a Prospective Real-World Observational Study (CONFIDENCE)

EPO-068

Lucy Abraham[1], Alexandre Urani[2], Giorgio Lambru[3], Richard B Lipton[4], Peter J Goadsby[5], Patricia Pozo-Rosich[6,7], Boryana Galabova[1], Kristina M Fanning[8], Feng Dai[9], Karin Hygge Blakeman[10]

[1]Pfizer R&D UK Ltd., Tadworth, Surrey; [2]Aptar Digital Health, Paris, France; [3]The Headache and Facial Pain Service, Guy's and St. Thomas' NHS Foundation Trust, London, UK; [4]Montefiore Medical Center and Albert Einstein College of Medicine, Bronx, NY, USA; [5]NIHR King's Clinical Research Facility, King's College Hospital/SLaM Biomedical Research Centre, King's College London, UK, and University of California, Los Angeles, CA, USA; [6]Headache and Neurological Pain Research Group, Vall d'Hebron Research Institute, Universitat Autònoma de Barcelona, Barcelona, Spain; [7]Headache and Craniofacial Pain Unit, Neurology Department, Vall d'Hebron University Hospital, Barcelona, Spain; [8]MIST Research, Wilmington, NC, USA; [9]Pfizer Inc, New York, NY USA; [10]Pfizer AB, Stockholm, Sweden

BACKGROUND

- Migraine is a chronic and disabling neurologic disorder characterized by typically unilateral, moderate to severe, pulsing headache.[1]
  - Other common symptoms include photophobia, phonophobia, and nausea.[1]
- Migraine represents a significant global burden that negatively impacts many facets of patient health and quality of life.[2]
- Rimegepant 75 mg orally disintegrating tablet (ODT) is a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist approved for the acute treatment of migraine and prevention of episodic migraine in adults.[3]
  - Four phase 3 randomized placebo-controlled clinical trials have demonstrated efficacy of rimegepant for the acute treatment of migraine based on the co-primary endpoints of freedom from pain and freedom from the most bothersome symptom at 2 h post dose.[4-7]
- CONFIDENCE (NCT06467370) is a prospective, real-world observational study in the United States evaluating the effectiveness of rimegepant 75 mg ODT for the acute treatment of migraine in adults.[8]

OBJECTIVE

- This interim analysis of the CONFIDENCE study assessed consistency of response to rimegepant 75 mg ODT for the acute treatment of migraine at the individual patient level.

METHODS

- This study was conducted with users of the Migraine Buddy® mobile app, a widely used tool for tracking headache symptoms, triggers, and treatment outcomes.[9]
- Eligible participants were adults (aged ≥18 years) with migraine who experienced 3–14 headache days in the last 30 days, received a prescription for rimegepant previously, and planned to use rimegepant during the next 30 days.
  - Participants were excluded if they were using rimegepant for preventive migraine treatment, were receiving concomitant treatment with onabotulinumtoxinA with any anti-CGRP (ligand or receptor) monoclonal antibody, were currently participating in a migraine-related clinical trial, or were diagnosed with cluster headache, post-traumatic headache, new daily persistent headache, hemicrania continua, or chronic daily headache.
- Using a custom-made interface in the Migraine Buddy app, participants completed:
  - A baseline survey capturing demographics and clinical characteristics.
  - A 28-day daily diary assessing time to meaningful pain relief, time to meaningful functional improvement, and treatment satisfaction.
    - "Meaningful" pain relief and functional improvement were subjectively determined by the participant as the time after rimegepant intake when they experienced reduced pain or improved function that they considered meaningful.
    - Satisfaction with treatment effectiveness (including pain reduction, attack duration, speed of action, cognitive symptoms, and overall), was measured using a 7-point rating scale ranging from extremely satisfied to extremely dissatisfied.
  - A questionnaire at study completion.
- Interim analyses assessed consistency of response, defined as achieving response in ≥2 of the first 3 rimegepant-treated attacks or in ≥3 of the first 4 rimegepant-treated attacks.
  - Response was defined in 3 independent ways:
    - Meaningful pain relief within 2 h.
    - Meaningful functional improvement within 2 h.
    - Reporting being "satisfied" or "extremely satisfied" with rimegepant effectiveness on pain reduction, attack duration, speed of action, cognitive symptoms, and overall satisfaction.
- Additional analyses examined consistency of response based on meaningful pain relief and functional improvement within 4 h.

RESULTS

PARTICIPANTS

- Most of the 146 eligible participants were female (92.5%), White (93.8%), overweight/obese (76.7%), and used preventive treatment (65.1%; **Table 1**).
- The population had a mean (SD) age of 40.1 (11.1) years, the mean (SD) number of headache days in the past 30 days was 7.4 (3.0), and 87% had a Migraine Disability Assessment score ≥11 (indicating moderate to severe disability; **Table 1**).

CONSISTENCY OF RESPONSE

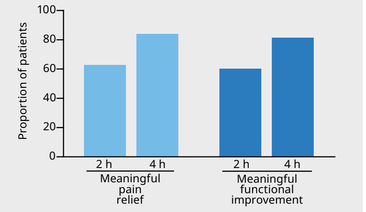
- Overall, 118 patients had ≥3 recorded migraine attacks that were treated with rimegepant during the study.
  - 62.7% of patients with ≥3 rimegepant-treated migraine attacks achieved meaningful pain relief within 2 h for ≥2 of the first 3 attacks and 83.9% achieved meaningful pain relief within 4 h for ≥2 of the first 3 attacks (**Figure 1**).
  - 60.2% of patients with ≥3 rimegepant-treated migraine attacks achieved meaningful improvement in function within 2 h for ≥2 of the first 3 attacks and 81.4% achieved meaningful improvement in function within 4 h for ≥2 of the first 3 attacks (**Figure 1**).
  - 75.4% of patients with ≥3 rimegepant-treated migraine attacks reported being "satisfied" or "extremely satisfied" with treatment overall for ≥2 of the first 3 attacks (**Figure 2**).
    - 74.6%, 74.6%, 64.4%, and 67.8% of patients reported being "satisfied" or "extremely satisfied" with pain reduction, attack duration, speed of action, and cognitive symptoms, respectively, for ≥2 of the first 3 attacks (**Figure 2**).

Table 1: Baseline demographics and clinical characteristics of all participants

	Rimegepant 75 mg ODT *N*=146
Age, mean (SD), y	40.1 (11.1)
Sex, *n* (%)	
Female	135 (92.5)
Male	11 (7.5)
Race, *n* (%)[a]	
White	137 (93.8)
Black or African American	3 (2.1)
Asian	3 (2.1)
American Indian or Alaska Native	3 (2.1)
Native Hawaiian or Other Pacific Islander	1 (0.7)
BMI category, *n* (%)	
Underweight	2 (1.4)
Normal	32 (21.9)
Overweight	41 (28.1)
Obese	71 (48.6)
Headache days, mean (SD), days	7.4 (3.0)
MIDAS score, median (IQR)	33.5 (16.8, 50.3)
MIDAS migraine disability grade, *n* (%)	
Little to mild	19 (13.0)
Moderate to severe	127 (87.0)
Any preventive medication, *n* (%)	95 (65.1)
Oral[b]	54 (56.8)
Anticonvulsant	20 (37.0)
Atogepant	17 (31.5)
Antidepressant	15 (27.8)
Injectable[b]	59 (62.1)
Fremanezumab	20 (33.9)
Galcanezumab	19 (32.2)
Erenumab	14 (23.7)

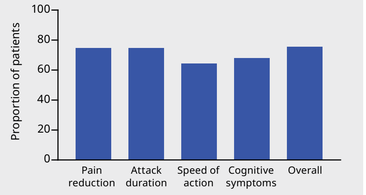
[a]Participants could select ≥1 race.
[b]The 3 most common medications were listed.
BMI=body mass index; IQR=interquartile range; MIDAS=Migraine Disability Assessment; ODT=orally disintegrating tablet

Figure 1: Consistency of response in ≥2 of the first 3 rimegepant-treated attacks



Based on 118 patients with ≥3 rimegepant-treated attacks.
h=hours post dose

Figure 2: Treatment satisfaction in ≥2 of the first 3 rimegepant-treated attacks



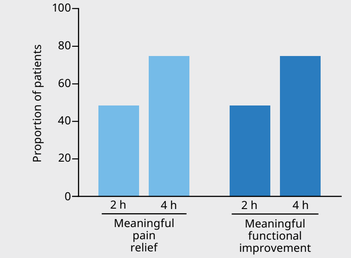
Based on 118 patients with ≥3 rimegepant-treated attacks.

- Overall, 95 patients had ≥4 recorded migraine attacks that were treated with rimegepant during the study.
  - 48.4% of patients with ≥4 rimegepant-treated migraine attacks achieved meaningful pain relief within 2 h for ≥3 of the first 4 attacks and 74.7% achieved meaningful pain relief within 4 h for ≥3 of the first 4 attacks (**Figure 3**).
  - 48.4% of patients with ≥4 rimegepant-treated migraine attacks achieved meaningful improvement in function within 2 h for ≥3 of the first 4 attacks and 74.7% achieved meaningful improvement in function within 4 h for ≥3 of the first 4 attacks (**Figure 3**).
  - 69.5% of patients with ≥4 rimegepant-treated migraine attacks reported being "satisfied" or "extremely satisfied" with treatment overall for ≥3 of the first 4 attacks (**Figure 4**).
    - 67.4%, 64.2%, 61.1%, and 63.2% of patients reported being "satisfied" or "extremely satisfied" with pain reduction, attack duration, speed of action, and cognitive symptoms, respectively, for ≥3 of the first 4 attacks (**Figure 4**).

CONCLUSIONS

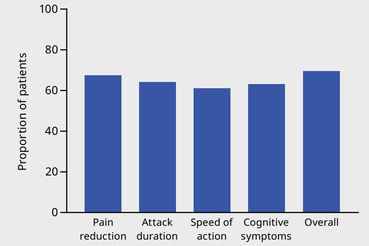
- Many patients achieved consistent response to rimegepant (≥2 out of 3 attacks) within 2 hours based on endpoints of meaningful pain relief (63%) and functional improvement (60%).
- Nearly half (48%) of patients achieved consistent response to rimegepant (≥3 out of 4 attacks) within 2 hours based on endpoints of meaningful pain relief and functional improvement.
- A majority of patients (61%–75% across satisfaction endpoints) reported being satisfied or extremely satisfied with rimegepant to treat their attacks.

Figure 3: Consistency of response in ≥3 of the first 4 rimegepant-treated attacks



Based on 95 patients with ≥4 rimegepant-treated attacks. h=hours post dose

Figure 4: Treatment satisfaction in ≥3 of the first 4 rimegepant-treated attacks



Based on 95 patients with ≥4 rimegepant-treated attacks. h=hours post dose

- A summary of response to rimegepant over the first 3 or 4 treated attacks is shown in **Table 2**.

Table 2: Summary of response to rimegepant treatment

Endpoint, *n* (%)	≥3 treated attacks *n*=118	≥4 treated attacks *n*=95
Pain relief within 2 h		
0 attacks	19 (16.1)	16 (16.8)
1 attack	25 (21.2)	12 (12.6)
2 attacks	31 (26.3)	21 (22.1)
3 attacks	43 (36.4)	16 (16.8)
4 attacks	N/A	30 (31.6)
Pain relief within 4 h		
0 attacks	5 (4.2)	2 (2.1)
1 attack	14 (11.9)	13 (13.7)
2 attacks	23 (19.5)	9 (9.5)
3 attacks	76 (64.4)	20 (21.1)
4 attacks	N/A	51 (53.7)
Functional improvement within 2 h		
0 attacks	19 (16.1)	15 (15.8)
1 attack	28 (23.7)	18 (18.9)
2 attacks	38 (32.2)	16 (16.8)
3 attacks	33 (28.0)	22 (23.2)
4 attacks	N/A	24 (25.3)
Functional improvement within 4 h		
0 attacks	6 (5.1)	2 (2.1)
1 attack	16 (13.6)	13 (13.7)
2 attacks	23 (19.5)	9 (9.5)
3 attacks	73 (61.9)	20 (21.1)
4 attacks	N/A	51 (53.7)
Overall treatment satisfaction		
0 attacks	14 (11.9)	8 (8.4)
1 attack	15 (12.7)	12 (12.6)
2 attacks	30 (25.4)	9 (9.5)
3 attack	59 (50.0)	23 (24.2)
4 attacks	N/A	43 (45.3)

Table shows how many of the initial 3 or 4 rimegepant-treated attacks met the specified endpoint.
N/A=not applicable

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DISCLOSURES

LA, FD, KHB: Employees of and own stock/options in Pfizer. **AU:** Employee of Aptar Digital Health, which was a paid consultant to Pfizer to conduct the study. **GL:** Travel, speaker, advisory board honoraria: AbbVie, Dr Reddy's Laboratories, Eli Lilly, Lundbeck, Novartis, Pfizer, Teva Pharmaceuticals. **RBL:** Editorial board: Neurology, Cephalalgia (not paid); senior advisor: Headache (not paid); research support: Marx Foundation, National Headache Foundation, NIH, US FDA; research grants, consultant/advisory board, honoraria: Aeon, Allergan, AbbVie, Amgen, Axsome, Dr Reddy's Laboratories, Eli Lilly, GSK, Ipsen, Lundbeck, Pfizer, Merck, Teva Pharmaceuticals, Vedanta; royalties: Informa, Wolff's Headache (8th ed); stock/stock options: Avon, Biohaven, CoolTech, Manistee. **PJG:** Consultant: Aeon Biopharma, AbbVie, Aurene, CoolTech LLC, Dr Reddy's Laboratories, Eli Lilly, Epalex, Kallyope, Linpharma, Lundbeck, Pfizer, PureTech Health LLC, Satsuma, Shiratronics, Teva Pharmaceuticals, Vial; personal fees for consultation: Gerson Lehrman Group, Guidepoint, SAI Med Partners, Vector Metric; fees for educational materials: CME Outfitters, WebMD; publishing royalties/fees: Massachusetts Medical Society, Oxford University Press, UptoDate, Wolters Kluwer. **PPR:** Consultant/speaker: AbbVie, Biohaven, Chiesi, Eli Lilly, Lundbeck, Medscape, Novartis, Pfizer, Teva Pharmaceuticals; research grants: AbbVie, AGAUR, EraNet Neuron, FEDER RIS3CAT, Instituto Investigación Carlos III, MICINN, Novartis, Teva Pharmaceuticals; funding for clinical trials: AbbVie, Biohaven, Eli Lilly, Lundbeck, Novartis, Teva Pharmaceuticals; Honorary Secretary: International Headache Society; editorial board: Revista de Neurologia; associate editor: Cephalalgia, Headache, Neurologia, Frontiers of Neurology; advisor: Scientific Committee, Editorial Board: Journal of Headache and Pain; member: Clinical Trials Guidelines Committee and Scientific Committee of the International Headache Society; editor: Guidelines for the Diagnosis and Treatment of Headache of the Spanish Neurological Society; founder: www.midolordecabeza.org, a platform to give information and tools to physicians and people who suffer from migraine and other headaches. **BG:** Employee of Pfizer. **KMF:** Managing director of MIST Research, which has received research funding from AbbVie, AESARA, Allay Lamp, Aptar, Java Health, Migraine Canada, NYC Langone Health.

ACKNOWLEDGMENTS

This study was sponsored by Pfizer. Medical writing support was provided by Matt Soulsby, PhD, CMPP, of Engage Scientific Solutions and was funded by Pfizer.

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Presented at the 11th Congress of the European Academy of Neurology (EAN), June 21–24, 2025, Helsinki, Finland