EPO-0582

Rimegepant for the Acute Treatment of Migraine in People With ≥1 Lapsed Triptans, With and Without Current Triptan Use, in the CONFIDENCE Study

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INTRODUCTION

- Triptans are a mainstay of acute migraine treatment, but not all patients can take triptans or respond well to them.[1]
- Rimegepant was specifically developed for the treatment of migraine and is approved as an acute or preventive therapy in several countries.[2,3]
- A recent randomized, placebo-controlled, phase 4 trial with open-label extension demonstrated single and multiple doses of rimegepant were efficacious for the acute treatment of migraine in patients who were unsuitable for triptans due to lack of efficacy, poor tolerability, or contraindication.[4,5]
- Since rimegepant is often used in people who have failed ≥1 triptan, its effectiveness in real-world users is clinically important.
- The prospective observational CONFIDENCE survey study assessed the effectiveness for the acute treatment of migraine over multiple attacks in the real world. At baseline, participants reported any previously used and discontinued triptans.
- This analysis used data from CONFIDENCE to explore the effectiveness of rimegepant in subgroups of participants with 1, 2, or ≥3 discontinued triptans and also by current triptan use.

METHODS

STUDY DESIGN

- CONFIDENCE (NCT06467370) was a prospective, observational, survey study in people who used rimegepant for the acute treatment of migraine in the United States.
- The study comprised screening and baseline questionnaires, a 28-day diary-based observation period, and an end of study questionnaire.

PARTICIPANTS

- Participants were recruited via the Migraine Buddy® app and then completed the study in an independent bespoke module.
- To enroll in CONFIDENCE, participants must have met the following criteria:
  - Age ≥18 years.
  - 3 to 14 headache days in the 30 days preceding enrollment.
  - 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 (most others were permitted).
  - No diagnoses of cluster headache, post-traumatic headache, new daily persistent headache, hemicrania continua, or chronic daily headache.

ANALYSES

- Demographics and clinical characteristics were collected in the screening and baseline questionnaires. This included current and discontinued triptan use and the reasons for these discontinuations. Each triptan was reported by name (eg, sumatriptan [Imitrex, Sumavel, Alsuma, Onzetra, Zembrace, Tosymra]).
- Participants reported on the occurrence, characteristics, treatment, and outcomes of any migraine attacks occurring on each day of the 28-day observation period.
- This analysis summarized patient-reported outcomes from the daily diary:
  - Achievement of meaningful pain relief (MPR) within 2 h or within 4 h of rimegepant treatment.
  - Achievement of meaningful functional improvement (MFI) within 2 h or within 4 h of rimegepant treatment.
- Odds ratios (ORs) for outcome achievement at the attack level by number of discontinued triptans were assessed using generalized linear mixed models with a logit link and a random intercept for participant.
  - Covariates included the number of rimegepant-treated migraine attacks reported in the study, age, gender, race, and current triptan use.

RESULTS

PARTICIPANT CHARACTERISTICS

- 132 (36%) participants had 1 discontinued triptan, 134 (36%) had 2 discontinued triptans, and 104 (28%) had ≥3 discontinued triptans. Among those who had ≥3 discontinued triptans, 68 participants had discontinued 3 triptans, 25 participants had discontinued 4 triptans, 5 participants had discontinued 5 triptans, and 6 participants had discontinued ≥6 triptans.
- The demographics and clinical characteristics by number of discontinued triptans are reported in **Table 1**.
- Participants with more discontinued triptans were incrementally older, a slightly higher proportion had a very severe Migraine Disability Assessment (MIDAS) score, and a slightly smaller proportion were current triptan users.

REASONS FOR TRIPTAN DISCONTINUATION

- The 4 most common reasons for triptan discontinuation were similar among participants with 1, 2, or ≥3 discontinued triptans: not reducing headache pain enough; side effects; not working as well as it used to; and not working quickly enough (**Figure 1**).
- These findings demonstrate the majority of prior triptan discontinuations were due to lack of efficacy or poor tolerability.

ATTACK CHARACTERISTICS

- Together, the 370 participants with ≥1 discontinued triptan reported data for 1948 rimegepant-treated migraine attacks. Participant characteristics and the number of attacks they contributed are presented in **Table 2**.
- A minority of rimegepant-treated attacks were also treated with a triptan (6%).
  - 81 (4%) attacks were treated with a triptan after taking rimegepant, including 38 attacks reported by participants with 1 discontinued triptan, 20 with 2, and 23 with ≥3.
  - A further 32 (2%) attacks were treated with a triptan before taking rimegepant, including 19 attacks reported by participants with 1 discontinued triptan, 8 with 2, and 5 with ≥3.

PROPORTION OF ATTACKS ACHIEVING POSITIVE TREATMENT OUTCOMES

- ≥50% of rimegepant-treated attacks in each subgroup achieved MPR or MFI within 2 h; ≥74% within 4 h. A decrease in the proportion of attacks achieving MPR and MFI was seen with increasing number of discontinued triptans (**Figure 2**).

ODDS OF ACHIEVING POSITIVE TREATMENT OUTCOMES

- In adjusted models, attacks reported by participants with a higher number of discontinued triptans had a lower odds of achieving positive treatment outcomes following rimegepant treatment.
- Attacks reported by participants with ≥3 discontinued triptans had 58% lower odds of achieving MPR within 2 h (OR: 0.42; 95% CI: 0.26, 0.67) and 54% lower odds of achieving MFI within 2 h (OR: 0.46; 95% CI: 0.30, 0.72) than attacks reported by participants with 1 discontinued triptan (*P*<0.001; **Figure 3**).
- Attacks reported by participants with ≥3 discontinued triptans had 50% lower odds of achieving MPR within 4 h (OR: 0.50; 95% CI: 0.27, 0.91) and 57% lower odds of achieving MFI within 4 h (OR: 0.43; 95% CI: 0.25, 0.75) than attacks reported by participants with 1 discontinued triptan (*P*<0.05; **Figure 4**).
- Attacks reported by participants with 2 discontinued triptans had 43% lower odds of achieving MFI within 4 h (OR: 0.57; 95% CI: 0.34, 0.97) than attacks reported by participants with 1 discontinued triptan (*P*<0.05; **Figure 4**).
- Attacks reported by participants who were current triptan users had 38% lower odds of achieving MPR within 2 h (OR: 0.62; 95% CI: 0.40, 0.95; *P*<0.05). Other outcomes were not significantly different between attacks reported by current and non-current users.

Table 1: Participant characteristics

n (%)[a]	Number of discontinued triptans 1 *n*=132	2 *n*=134	≥3 *n*=104
Age, mean years (SD)	38.2 (10.7)	39.0 (10.0)	42.1 (11.7)
Gender, Female	115 (87.1)	117 (87.3)	90 (86.5)
Race, White	120 (90.9)	123 (91.8)	97 (93.3)
BMI, mean (SD), kg/m^2	30.2 (7.4)	30.6 (7.8)	29.1 (7.5)
Headache days in the past 30 days			
Median (Q1, Q3)	8 (5, 11)	8 (5, 10)	8 (5, 10)
3	6 (4.5)	6 (4.5)	7 (6.7)
4 to 7	45 (34.1)	60 (44.8)	40 (38.5)
8 to 14	81 (61.4)	68 (50.7)	57 (54.8)
MIDAS classification			
Grade I: Little or no disability (score ≥5)	4 (3.0)	7 (5.2)	6 (5.8)
Grade II: Mild disability (score 6 to 10)	9 (6.8)	7 (5.2)	7 (6.7)
Grade III: Moderate disability (score 11 to 20)	25 (18.9)	28 (20.9)	23 (22.1)
Grade IVa: Severe disability (score 21 to 40)	45 (34.1)	39 (29.1)	26 (25.0)
Grade IVb: Very severe disability (score ≥41)	49 (37.1)	53 (39.6)	42 (40.4)
Current triptan user			
Yes	59 (44.7)	25 (18.7)	19 (18.3)
No	73 (55.3)	109 (81.3)	85 (81.7)
Current preventive use			
None	18 (13.6)	21 (15.7)	12 (11.5)
Oral preventive medication only	19 (14.4)	28 (20.9)	16 (15.4)
OnabotulinumtoxinA	47 (35.6)	44 (32.8)	37 (35.6)
CGRP mAb	48 (36.4)	41 (30.6)	39 (37.5)

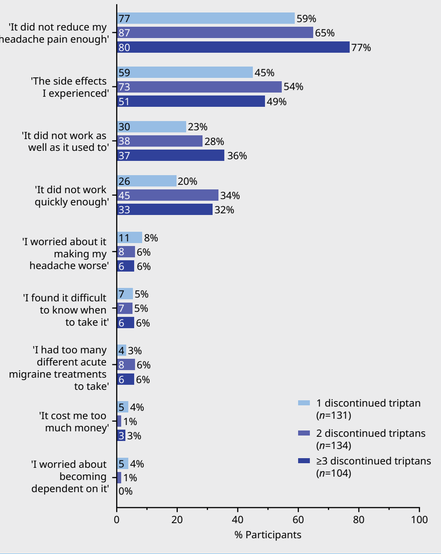
[a] Except where otherwise indicated.
BMI=body mass index; CGRP mAb=calcitonin gene-related peptide monoclonal antibody; Q=quartile; MIDAS=Migraine Disability Assessment

Table 2: Participant characteristics for all rimegepant-treated attacks

n (%)	Attacks[a] *n*=1948
Gender, Female	1699 (87.2)
Race, White	1787 (91.7)
Number of rimegepant-treated migraine attacks in the study	
1 to 5	735 (37.7)
6 to 10	953 (48.9)
11 to 24	260 (13.3)
Number of discontinued triptans	
1	662 (34.0)
2	719 (36.9)
≥3	567 (29.1)
Current triptan user	
Yes	538 (27.6)
No	1410 (72.4)

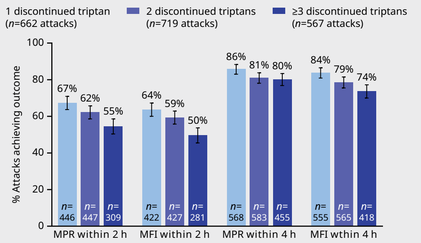
[a] Shows participant characteristics for all rimegepant-treated migraine attacks reported by participants with ≥1 discontinued triptan.

Figure 1: Reasons for discontinuing ≥1 triptan



Participants could select >1 reason. Numbers at the base of each bar show the number of participants
Numbers <3 are not shown due to limited bar size.

Figure 2: Proportion of attacks achieving positive treatment outcomes by number of discontinued triptans

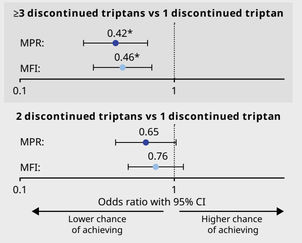


Numbers at the base of each bar show the number of attacks.
MFI=meaningful functional improvement; MPR=meaningful pain relief

CONCLUSIONS

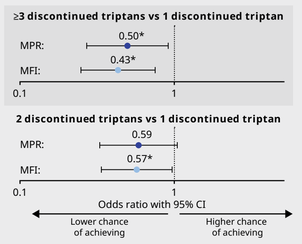
- In this real-world observational study, most rimegepant-treated attacks (≥50%) achieved meaningful pain relief or meaningful functional improvement within 2 h (≥74% within 4 h) across participants who had discontinued 1, 2, or ≥3 triptans.
- Attacks treated with rimegepant by participants with a higher number of discontinued triptans had lower odds of achieving positive treatment outcomes than attacks treated by participants who had discontinued just 1 triptan.
- These results indicate that the number of triptan discontinuations may help characterize subpopulations of patients with migraine who differ in their response to acute treatments such as rimegepant. Further characterization of these subpopulations could be explored in future studies.

Figure 3: Odds of achieving positive treatment outcomes within 2 h of rimegepant treatment by number of discontinued triptans



* *P*<0.05
Odds calculated at the attack level. MFI=meaningful functional improvement; MPR=meaningful pain relief

Figure 4: Odds of achieving positive treatment outcomes within 4 h of rimegepant treatment by number of discontinued triptans



* *P*<0.05
Odds calculated at the attack level. MFI=meaningful functional improvement; MPR=meaningful pain relief

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DISCLOSURES

RBL: Research support: NIH, FDA; research grants, consultant, advisory board, or honoraria: Allergan/AbbVie, Amgen, Axsome, Dr Reddy's Laboratories, Eli Lilly, GlaxoSmithKline, Ipsen, Linpharma, Lundbeck, Pfizer, Merck, Teva, Vedanta; royalties: Informa, Wolff's Headache (8th ed; Oxford University Press, 2009); stock options: Biohaven Pharmaceuticals, CoolTech, Manistee, NuVieBio. **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 advisory boards: AbbVie, Dr Reddy's Laboratories, Eli Lilly, Lundbeck, Novartis, Pfizer, Teva. **PJG**: Consultant: AbbVie, CoolTech LLC, Dr Reddy's, Epalex, Ipsen, Kallyope, Linpharma, Lundbeck, Orion Pharma, Pfizer, PureTech Health LLC, Satsuma, Scilex Pharmaceuticals, Seaport Therapeutics, Septurna, Teva Pharmaceuticals;advisor: Gerson Lehrman Group, Guidepoint, SAI Med Partners; educational materials: CME Outfitters, WebMD; publishing royalties/fees: Massachusetts Medical Society, Oxford University Press, UptoDate, Wolters Kluwer. **PP-R**: Consultant/speaker: AbbVie, Almirall, Dr. Reddy's, Eli Lilly, Lundbeck, Medscape, Novartis, Otsuka Pharmaceuticals, Pfizer, Teva; research group received research grants from AbbVie, AGAUR, EraNet Neuron, FEDER RIS3CAT, Instituto Investigación Carlos III, Novartis, Teva; clinical trials funding: AbbVie, Biohaven, Eli Lilly, Lundbeck, Novartis, Teva; founder of www.midoloredecabeza.org, a platform to give information and tools to physicians and people who suffer from migraine and other headaches. **TJS**: Consultant: AbbVie, Lundbeck, Salvia, royalties; UpToDate; research support: AbbVie, American Heart Association, Flinn Foundation, Henry Jackson Foundation, National Headache Foundation, National Institutes of Health, Patient Centered Outcomes Research Institute, Pfizer, US Department of Defense; stock options/equity: Allevalux and Nocira. **KMF**: Owner/managing director of MIST Research and Statistical Consulting, which has received research funding from AbbVie, Aptar,CoolTech, Ipsen, The Headache & Migraine Policy Forum, NYC Langone Health, Pfizer, Scilex Holding, UC Irvine; advisory board: Pfizer; grants: Bill and Joan Alfond Foundation to the Mass General Brigham Department of Neurology. **LA, KHB**: Employees of and own stock/options in Pfizer.

ACKNOWLEDGMENTS

This study was sponsored by Pfizer. Medical writing support was provided by Jennifer Bodkin of Engage Scientific Solutions and was funded by Pfizer.

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Presented at the 12th Congress of the European Academy of Neurology (EAN), June 27–30, 2026, Geneva, Switzerland