Prospective, real-world evidence of meaningful pain relief, return to function, and satisfaction among patients with migraine on acute rimegepant treatment alone or with concomitant preventive migraine medication

PO-290

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

[1]Pfizer AB., Stockholm, Sweden; [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, New York, 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, Los Angeles, CA, USA; [6]Headache and Neurological Pain Research Group, Vall d'Hebron Research Institute, Universitat Autònoma de Barcelona, Barcelona, Spain, Headache and Craniofacial Pain Unit, Neurology Department, Vall d'Hebron University Hospital, Barcelona, Spain; [7]Department of Neurology, Mayo Clinic, Scottsdale, Arizona, USA; [8]MIST Research, Wilmington, NC, USA; [9] Pfizer R&D UK Ltd., Tadworth, Surrey

OBJECTIVE

To evaluate the effectiveness of acute rimegepant treatment in patients with migraine across 4 subgroups: 1. no concomitant preventive medication (rimegepant only); 2. oral migraine preventive medications (OMPMs); 3. onabotulinumtoxinA (BTX); and 4. anti-calcitonin gene-related peptide monoclonal antibodies (CGRP mAbs)

CONCLUSIONS

- Patients treating migraine attacks with rimegepant, independent of preventive treatment use, reported meaningful pain relief, a return to normal function, and high satisfaction
- It remains uncertain if the differences between subgroups are due to selection bias or reflect true variations in the effectiveness of rimegepant combined with preventive medication for the acute treatment of migraine

BACKGROUND

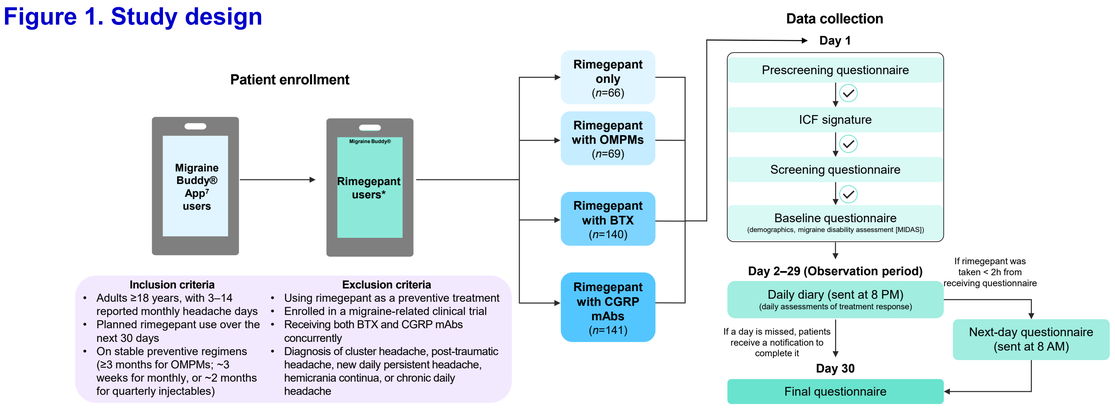
- Migraine, a chronic, disabling neurovascular disorder, is characterized by recurrent moderate-to-severe headache, often accompanied by nausea, photophobia, and phonophobia[1-3]
- Rimegepant, an oral CGRP receptor antagonist, is approved for the acute treatment of migraine and has demonstrated efficacy in randomized controlled trials[4,5]
- CONFIDENCE (NCT06467370)[6] is a prospective, real-world observational study evaluating the effectiveness of rimegepant for the acute treatment of migraine in adults

METHODS

Study design

Adult patients prescribed oral rimegepant for acute migraine treatment were enrolled via the Migraine Buddy® app[7] in USA for a study period of 30 days **(Figure 1)**

Figure 1. Study design



*Eligible patients were enrolled via the Migraine Buddy® mobile app, and their responses were collected in a bespoke interface as an add-on in the Migraine Buddy app.
The subgroups included patients on rimegepant with or without preventives. Patients on preventives were not randomized to prevention use; therefore, they are not comparable. Patients completed all questionnaires from Day 1 through Day 30. Patients completed a Day 1 baseline questionnaire (demographics and migraine disability assessment [MIDAS]), Day 2–29 daily assessment report (daily diary), and a Day 30 questionnaire.
Abbreviations: App, application, BTX, botox; CGRP mAbs, anti-calcitonin gene-related peptide monoclonal antibodies; MIDAS, migraine disability assessment; OMPMs, oral migraine preventive medications.

Key outcomes assessed

Proportion of patients (survey respondents) within each subgroup achieving a response in at least 66.7% of attacks (2 out of 3 attacks) in up to 10 rimegepant-treated attacks for:

- Meaningful pain relief (MPR) within 2 and 4 hours
- Return to function (RTF) within 2 and 4 hours
- Satisfied/extremely satisfied with rimegepant across different satisfaction domains (pain reduction, attack duration, speed of action, cognitive symptoms and overall satisfaction)

RESULTS

Key demographic and baseline characteristics

- Of the 416 eligible patients (mean age: 40 years; female: 86.1%; White: 90.4%), majority reported moderate-to-severe disability (rimegepant only [90.9%]; with OMPMs [94.2%]; with BTX [92.9%]; with CGRP mAbs [84.4%]) at baseline **(Table 1)**
- The median number of headache days reported in the study interface was 8 (interquartile range [IQR]: 5, 10) at baseline and 7 (IQR: 5, 10) during the study

Rimegepant effectiveness across subgroups

- Across all endpoints, patients in the rimegepant only subgroup had the highest response rates, while those in the rimegepant with CGRP mAbs subgroup had the lowest response rates
  - **MPR** ranged from 44.7%–65.2% at 2 hours and 78.7%–83.3% at 4 hours **(Figure 2A)**
  - **RTF** ranged from 39.7%–68.2% at 2 hours and 68.8%–84.8% at 4 hours **(Figure 2B)**
  - **Satisfaction** with rimegepant across different domains are reported in **Figure 2C**; proportion of patients within each subgroup being satisfied overall ranged from 55.3%–77.3%. All subgroups on preventives were most satisfied with pain reduction.

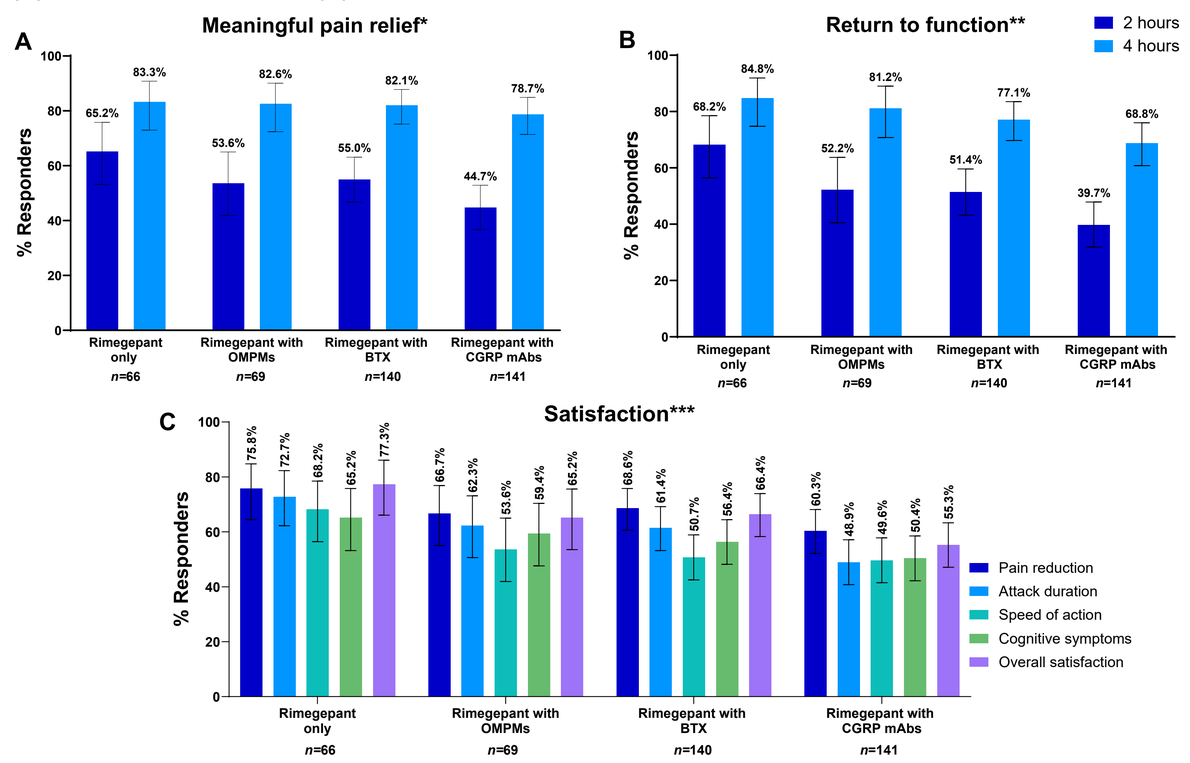
RESULTS

Table 1. Baseline demographics and clinical characteristics

N = 416 patients reporting ≥1 rimegepant-treated attack	Rimegepant only (*n*=66)	Rimegepant with OMPMs (*n*=69)	Rimegepant with BTX (*n*=140)	Rimegepant with CGRP mAbs (*n*=141)
Age, mean (SD), y	40 (12)	40 (10)	40 (11)	40 (11)
Female, *n* (%)	56 (84.8)	59 (85.5)	125 (89.3)	118 (83.7)
Race, *n* (%)				
White Caucasian	61 (92.4)	61 (88.4)	124 (88.6)	130 (92.2)
Hispanic or Latino	6 (9.1)	5 (7.2)	9 (6.4)	10 (7.1)
BMI categories, *n* (%)				
Underweight	1 (1.5)	0	1 (0.7)	3 (2.1)
Normal	24 (36.4)	8 (11.6)	40 (28.6)	37 (26.2)
Overweight	21 (31.8)	21 (30.4)	45 (32.1)	31 (22.0)
Obese	20 (30.3)	40 (58.0)	54 (38.6)	70 (49.6)
BMI score, mean (SD)	27.88 (7.0)	32.80 (8.1)	28.96 (6.2)	30.01 (8.3)
MIDAS grade, *n* (%)				
Little-to-mild disability	6 (9.1)	4 (5.8)	10 (7.1)	22 (15.6)
Moderate-to-severe disability	60 (90.9)	65 (94.2)	130 (92.9)	119 (84.4)

Abbreviations: BMI, body mass index; BTX, botox; CGRP mAbs, anti-calcitonin gene-related peptide monoclonal antibodies; MIDAS, Migraine Disability Assessment; OMPMs, oral migraine preventive medications; SD, standard deviation.

Figure 2. Effectiveness of rimegepant (% of patients achieving a response in ≥66.7% of attacks), with or without concomitant migraine preventive medications, in acute migraine treatment (A) Pain relief, (B) return to function, and (C) satisfaction across various domains



"*n*" refers to the number of respondents in each preventive background group of a total of 416 patients with at least one rimegepant-treated attack. Analyses included the proportion of respondents achieving a response in at least 66.7% of attacks in up to 10 rimegepant-treated attacks. Data are represented as mean (%) with 95% CI.
* When the level of headache pain reduces to a degree that is meaningful to the patients, along with or prior to pain freedom.
** Improvement in functioning to perform daily activities using functional disability scale.
*** Includes responses in which patients indicated they were satisfied or extremely satisfied (two highest levels of a 7-level likert scale).
Abbreviations: BTX, botox; CGRP mAbs, anti-calcitonin gene-related peptide monoclonal antibodies; CI, confidence interval; OMPMs, oral migraine preventive medications.

References: 1. Ferrari MD, et al., *Nat Rev Dis Primers*. 2022; 8:2. 2. Agosti R, *Headache. 2018;* 58(Suppl 1):17–32. 3. Headache Classification Committee of the International Headache Society (IHS) The International Classification of Headache Disorders,3rd Edition. *Cephalalgia*. 2018, 38:1–211. 4. Blair HA, *CNS Drugs*. 2023; 37:255–265. 5. Croop R, et al., *Lancet*. 2019; 394:737–745. 6. https://clinicaltrials.gov/study/NCT06467370 7. MigraineBuddy. https://migrainebuddy.com/ (accessed July 21, 2025).

Disclosures: **KHB** and **LA** are employees and shareholders of Pfizer; **AU** is an employee of Aptar Digital Health which acted as a paid party to conduct the study; **GL** reports, over the last 36 months, personal fees for lecturing and taking part in advisory board from Pfizer, Teva, Eli Lilly, Lundbeck, Dr Reddy's, Abbvie; **RBL** has received research support from the National Institutes of Health, the FDA, and the National Headache Foundation. He serves as consultant, advisory board member, or has received honoraria or research support from AbbVie/Allergan, Amgen, Axsome, Biohaven, Eli Lilly, GlaxoSmithKline, Lilly, Lundbeck, Merck, Novartis, NuVieBio, Pfizer, Teva, Vector, and Vedanta Research; receives royalties from Wolff's Headache, 8th edition (Oxford University Press, 2009) and Informa; and holds stock/options in Biohaven, Cooltech, Mainistee, and NuVieBio; **PJG** reports, over the last 36 months, personal fees for consulting from Aeon Biopharma, Abbvie, Aurene, CoolTech LLC, Dr Reddy's, Eli-Lilly and Company, Epalex, Kallyope, Linpharma, Lundbeck, Pfizer, PureTech Health LLC, Satsuma, Shiratronics, Teva Pharmaceuticals, and Vial, and personal fees for advice through Gerson Lehrman Group, Guidepoint, SAI Med Partners, Vector Metric, and fees for educational materials from CME Outfitters and WebMD, and publishing royalties or fees from Massachusetts Medical Society, Oxford University Press, UptoDate and Wolters Kluwer; **PPR** reports over the last 36 months, personal fees for medical education or consulting from AbbVie, Dr. Reddy's, Eli Lilly, Lundbeck, Medscape, Novartis, Organon, Pfizer and Teva. Her research group has received research grants from AbbVie, Novartis and Teva; as well as, Instituto Salud Carlos III, EraNet Neuron, European Regional Development Fund (001-P-001682) under the framework of the FEDER Operative Programme for Catalunya 2014-2020 - RIS3CAT; and has received funding for clinical trials from AbbVie, Amgen, Biohaven, Eli Lilly, Novartis, Teva; **TJS** reports, over the last 36 months, personal fees for consulting from Consulting: AbbVie, Allergan, Amgen, Axsome, Collegium, Eli Lilly, Linpharma, Lundbeck, Salvia, Satsuma, Scilex, and Theranica. He has received royalties from UpToDate and holds/held stock options in Allevalux, Aural Analytics, and Nociria. His employer has received research grants on his behalf from American Heart Association, Flinn Foundation, Henry Jackson Foundation, National Headache Foundation, National Institutes of Health, Patient Centered Outcomes Research Institute, Pfizer, Spark Neuro, and United States Department of Defense; **KMF** is managing director of MIST Research, which has received research funding from AbbVie, Allay Lamp, Aptar, Juva Health, Pfizer, and NYC Langone Health.

Acknowledgements: This study was sponsored by Pfizer. Medical writing support was provided by Priyanka Jaisar, PhD, and editorial support was provided by Kripa Madnani, PhD, Archana Patkar, PhD, ISMPP CMPP™, Xiaoyan Song, MD, and Anita Kumar, PhD (all employees of Pfizer).