PO-284

Efficacy and Safety of Rimegepant for the Acute Treatment of Migraine in Hispanic or Latino Adults: Post-hoc Analysis of 3 Randomized, Placebo-Controlled Clinical Trials

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INTRODUCTION

- Rimegepant is a small-molecule, oral, calcitonin gene-related peptide (CGRP) receptor antagonist approved for the acute treatment of migraine and the prevention of episodic migraine.[1,2]
- The safety and efficacy of rimegepant for the acute treatment of migraine was established in three phase 3 clinical trials in the United States.[3-5]
  - These studies predominantly enrolled patients of non-Hispanic or Latino ethnicity and White race (nHLW).[3-5] Assessing treatment outcomes in people of different races and ethnicities is important to identify potential healthcare disparities.[6,7]

OBJECTIVE

- This exploratory post-hoc analysis pooled data from the US-based phase 3 trials to evaluate the safety and efficacy of rimegepant for the acute treatment of migraine in 3 groups: (1) patients of Hispanic or Latino ethnicity (HL), (2) nHLW patients, and (3) patients of non-Hispanic or Latino ethnicity and Black/African American race (nHLB/AA).

METHODS

STUDY DESIGN

- Data were pooled from three phase 3, multicenter, double-blind, randomized, placebo-controlled trials conducted in the United States (NCT03235479; NCT03237845; NCT03461757).[3-5]
- All trials had a similar design. After completing a 28-day screening period, patients treated a single migraine attack of moderate to severe pain intensity during an up to 45-day treatment period. Patients had an end-of-study visit within 7 days of treatment.
- Key inclusion criteria: Aged ≥18 years old, ≥1-year history of migraine (with or without aura), untreated migraine attacks lasting 4–72 h, 2 to 8 migraine attacks with moderate or severe pain intensity/month in the 3 months prior to screening, and <15 headache days/month in the 3 months prior to screening.
- Preventive therapy was permitted if stable in the 3 months prior to screening. In each trial, patients were stratified by use of preventive migraine medication (yes/no) then randomized 1:1 to rimegepant 75 mg or placebo.

MEASURES

- Patients completed electronic diaries (eDiaries) to document their migraine characteristics (pain, symptoms, and functional disability) and medication use prior to taking study treatment, and at regular intervals up to 48 h post treatment.
- Rescue medication could be taken after the 2 h post treatment assessment, but no efficacy endpoints could be achieved after it was taken.

ANALYSES

- Coinciding with the primary endpoints in the original trials, the co-primary endpoints in this exploratory post-hoc analysis compared rimegepant- vs placebo-treated groups within each group for:
  - Proportion with pain freedom at 2 h post treatment.
  - Proportion with freedom from their most bothersome symptom (MBS) noted pretreatment (specifically photophobia, phonophobia, or nausea) at 2 h post treatment.
- The proportion of patients with pain relief, pain freedom, and freedom from MBS at each timepoint following treatment (various from 15 min to 48 h) were supportive endpoints.
- Each efficacy endpoint was assessed using a Mantel–Haenszel risk estimation stratified by preventive medication use.
- Safety analyses described adverse events (AEs) reported from the time of treatment to 7 days post treatment.
- All P values are nominal and descriptive. There were no adjustments for multiplicity.

RESULTS

- 3553 patients took part in the 3 pooled trials. Of these, 546 (15%) were HL, 2215 (62%) nHLW, and 657 (18%) nHLB/AA.
- Key baseline demographics and clinical characteristics by treatment are shown in **Table 1**.
  - Age, sex, mean number of moderate to severe attacks/month, and historical MBS were broadly comparable across groups and treatments.

Table 1: Key demographics and clinical characteristics

	Hispanic or Latino ethnicity		Non-Hispanic or Latino ethnicity			
			White race		Black or African American race	
	Rimegepant n=254	Placebo n=292	Rimegepant n=1102	Placebo n=1113	Rimegepant n=342	Placebo n=315
Age, mean (SD), y	39.5 (11.8)	39.5 (12.1)	41.1 (12.6)	41.1 (12.5)	38.9 (10.7)	38.3 (10.2)
Sex, n (%)						
Female	222 (87.4)	260 (89.0)	953 (86.5)	973 (87.4)	293 (85.7)	252 (80.0)
Male	32 (12.6)	32 (11.0)	149 (13.5)	140 (12.6)	49 (14.3)	63 (20.0)
Race, n (%)						
White	220 (86.6)	265 (90.8)	1102 (100.0)	1113 (100.0)	0	0
Black or African American	23 (9.1)	16 (5.5)	0	0	342 (100.0)	315 (100.0)
Other	9 (3.5)	11 (3.8)	0	0	0	0
Not reported	2 (0.8)	0	0	0	0	0
Number of moderate to severe attacks/month, mean (SD)	4.6 (1.8)	4.5 (1.7)	4.6 (1.8)	4.6 (1.8)	4.8 (1.8)	4.9 (1.8)
Historical MBS, n (%)						
Photophobia	172 (67.7)	164 (56.2)	601 (54.5)	614 (55.2)	205 (59.9)	183 (58.1)
Nausea	47 (18.5)	71 (24.3)	316 (28.7)	299 (26.9)	62 (18.1)	69 (21.9)
Phonophobia	35 (13.8)	57 (19.5)	185 (16.8)	199 (17.9)	73 (21.3)	63 (20.0)
Not reported	0	0	0	1 (0.1)	2 (0.6)	0

Includes all patients who took study treatment. MBS=most bothersome symptom

PRIMARY ENDPOINT ANALYSES

- At 2 h post treatment with rimegepant, pain freedom was achieved in 20% of HL, 19% of nHLW, and 24% of nHLB/AA patients (**Table 2**).
  - The treatment difference compared with placebo was 6% for HL (nominal P=0.0514), 9% for nHLW (nominal P<0.001), and 5% for nHLB/AA (nominal P=0.115) patients.

Table 2: Co-primary endpoints

	Hispanic or Latino ethnicity			Non-Hispanic or Latino ethnicity					
				White race			Black or African American race		
Stratified risk (95% CI)	Rimegepant n=251	Placebo n=286	Diff.	Rimegepant n=1090	Placebo n = 1103	Diff.	Rimegepant n=336	Placebo n=308	Diff.
Pain freedom at 2 h post treatment	19.9 (14.9, 24.8) [n=50/251]	13.6 (9.6, 17.6) [n=39/286]	6.3 (0.0, 12.6) P=0.0514	18.9 (16.6, 21.2) [n=206/1090]	10.2 (8.5, 12.1) [n=113/1103]	8.6 (5.7, 11.6) P<0.001	23.8 (19.1, 28.1) [n=80/336]	18.5 (14.2, 22.9) [n=57/308]	5.1 (–1.2, 11.3) P=0.1115
Freedom from MBS at 2 h post treatment	31.8 (26.1, 37.6) [n=80/251]	31.8 (26.4, 37.2) [n=91/286]	0.0 (–7.9, 7.9) P=0.9992	35.2 (32.4, 38.0) [n=384/1090]	22.8 (20.4, 25.3) [n=253/1103]	12.4 (8.6, 16.1) P<0.001	42.9 (37.6, 48.2) [n=145/336]	35.0 (29.6, 40.2) [n=109/308]	7.9 (0.5, 15.4) P=0.038

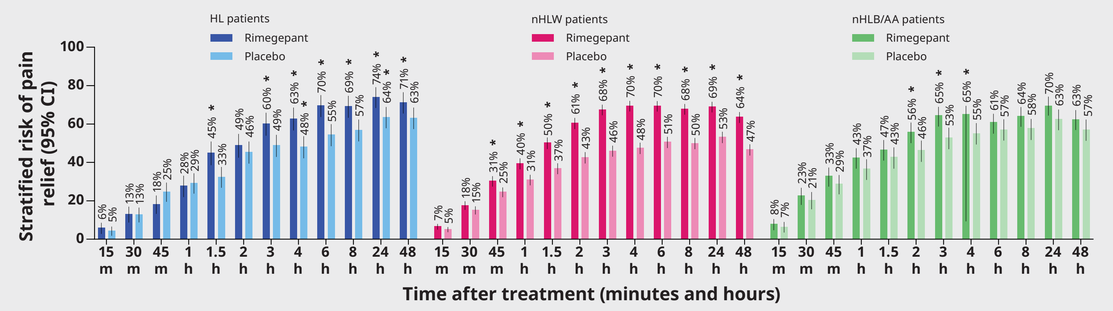
P values are nominal. Diff.=difference; MBS=most bothersome symptom (prior to treatment)

- At 2 h post treatment with rimegepant, freedom from MBS was achieved by 32% of HL, 35% of nHLW, and 43% of nHLB/AA patients (**Table 2**).
  - The treatment difference compared with placebo was 0% for HL (nominal P=0.9992), 12% for nHLW (nominal P<0.001), and 8% for nHLB/AA (nominal P=0.038) patients.

TIME COURSE ANALYSES

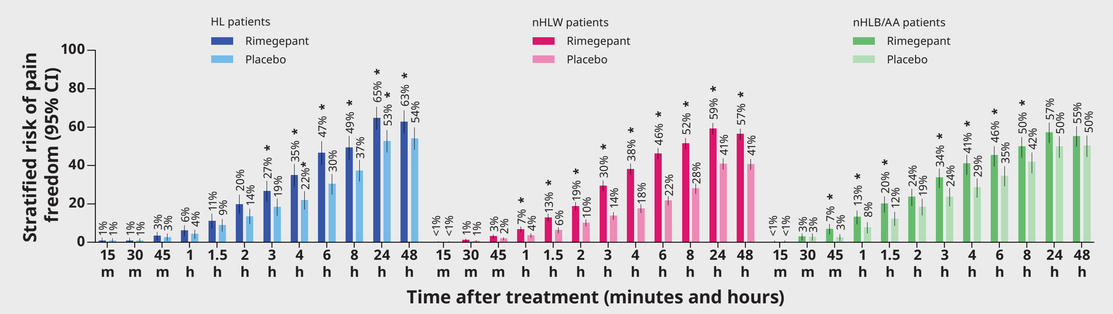
- Over 48 h post treatment, pain relief, pain freedom, and freedom from MBS were achieved by higher proportions of patients who took rimegepant vs placebo in all groups (**Figures 1, 2, and 3**).
- In HL patients, consistent nominal significance for the post-treatment difference (rimegepant vs placebo) was observed from 3 h for pain relief, 3 h for pain freedom, and 4 h for freedom from MBS.
  - This was later than in nHLW patients, who had consistent nominal significance for all 3 endpoints beginning 45 min to 1 h post treatment.
- At 24 and 48 h, numerically greater proportions of HL patients had pain relief, pain freedom, and freedom from MBS relative to the same measures in nHLW or nHLB/AA patients.

Figure 1: Time course of post-treatment pain relief



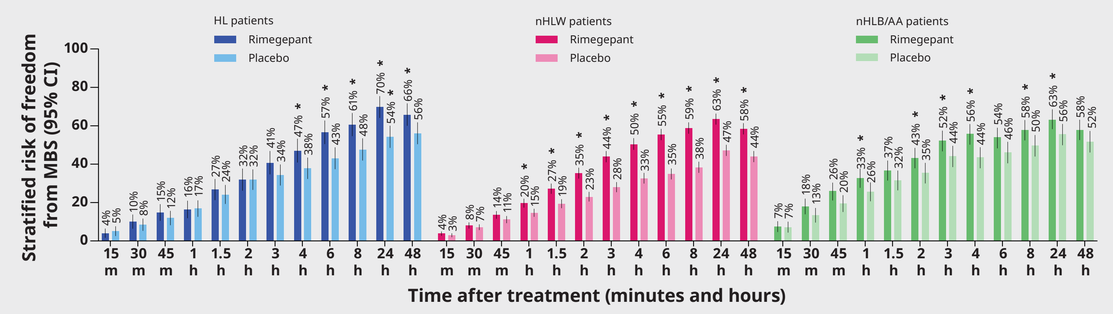
*P<0.05. HL=Hispanic or Latino ethnicity; nHLB/AA=non-Hispanic or Latino ethnicity and Black or African American race; nHLW=non-Hispanic or Latino ethnicity and White race

Figure 2: Time course of post-treatment pain freedom



*P<0.05. HL=Hispanic or Latino ethnicity; nHLB/AA=non-Hispanic or Latino ethnicity and Black or African American race; nHLW=non-Hispanic or Latino ethnicity and White race

Figure 3: Time course of post-treatment freedom from MBS



*P<0.05. HL=Hispanic or Latino ethnicity; MBS=most bothersome symptom (pretreatment); nHLB/AA=non-Hispanic or Latino ethnicity and Black or African American race; nHLW=non-Hispanic or Latino ethnicity and White race

SAFETY

- The incidence of AEs was broadly comparable in rimegepant- and placebo-treated patients across all 3 patient groups (**Table 3**).

Table 3: Adverse events post treatment

	Hispanic or Latino ethnicity		Non-Hispanic or Latino ethnicity			
			White race		Black or African American race	
Adverse events	Rimegepant n=254	Placebo n=292	Rimegepant n=1102	Placebo n=1113	Rimegepant n=342	Placebo n=315
≥1 AE	32 (12.6)	24 (8.2)	108 (9.8)	98 (8.8)	38 (11.1)	26 (8.3)
≥1 severe AE	2 (0.8)	0	3 (0.3)	2 (0.2)	1 (0.3)	1 (0.3)
≥1 serious AE	0	1 (0.3)	1 (0.1)	1 (0.1)	0	0
≥1 AE related to study drug	22 (8.7)	14 (4.8)	59 (5.4)	53 (4.8)	23 (6.7)	16 (5.1)

AE=adverse event

CONCLUSIONS

- This study is the first and only study to have specifically evaluated the safety and efficacy of an oral CGRP receptor antagonist for the acute treatment of migraine in HL patients.
- In data pooled from 3 US-based phase 3 clinical trials, rimegepant efficacy was observed in HL and nHL groups.
- In HL patients, pain freedom and freedom from MBS were nominally significant vs placebo at 3 to 4 h post treatment, then sustained through 48 h.
- This hints at a possible delay in the response to rimegepant, particularly in comparison to nHLW patients who had consistent nominal significance from 45 min to 1 h post treatment.
- Statistical findings should be interpreted with caution.
- Rimegepant was well tolerated in all 3 patient groups, with a broadly similar incidence of AEs relative to placebo.

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DISCLOSURES

JRV: Consulting: AbbVie, Alpha Sights Ltd, Biodelivery Sciences International Inc, Guidepoint Global, Impel Pharmaceutics Inc, Pfizer, Slingshot Insights Inc, Tegus by AlphaSense, Theranica, Third Bridge; speakers bureau: AbbVie, Pfizer Global. **JL:** Affiliated with Pfizer. **CA, MF, MTS:** Employees of and own stock/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 2025 International Headache Congress (IHC), September 10–13, 2025, Sao Paulo, Brazil