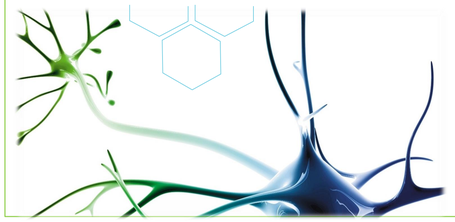


Rimegepant Preference and Improved Clinical Global Impression of Change Among Adults With Triptan Treatment Failure

Ira M. Turner, MD[1]; William T. Seidel, PhD[2]; Jelena M. Pavlovic, MD, PhD[3,4]; Richard B. Lipton, MD[3,4]; Christopher M. Jensen, PharmD[2]; Alexandra Thiry, PhD[2]; Meghan Lovegren, BS[2]; Charles M. Conway, PhD[2]; Vladimir Coric, MD[2]; Robert Croop, MD[2]

1 Island Neurological Associates, Plainview, NY, USA; 2 Biohaven Pharmaceuticals, New Haven, CT, USA; 3 Albert Einstein College of Medicine, Bronx, NY, USA; 4 Montefiore Headache Center, Bronx, NY, USA

Background

- Preference of medication, satisfaction with medication, and clinical global impression of change (CGI-C) are clinically meaningful outcome measures in trials of medications for the acute treatment of migraine
- Rimegepant is a Food and Drug Administration–approved, orally administered small-molecule calcitonin gene-related peptide receptor antagonist that has demonstrated efficacy and safety in the acute and preventive treatment of migraine across multiple randomized, placebo-controlled clinical trials[1-5]
- Preference of medication, satisfaction with medication, and CGI-C have not been previously evaluated in rimegepant-treated subjects with a history of triptan treatment failure

Purpose

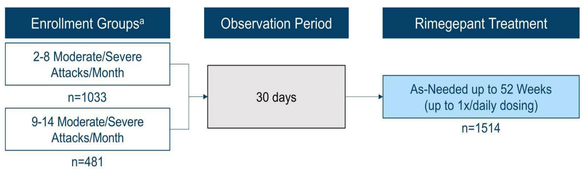
- Assess preference for rimegepant, satisfaction with rimegepant, and CGI-C in adults with a history of triptan treatment failure using oral rimegepant as needed up to once daily for the acute treatment of migraine for up to 1 year

Methods

- This was a multicenter, open-label, long-term safety study (NCT03266588) of oral rimegepant 75 mg dosed up to once daily for up to 1 year (Figure 1)

Figure 1. Study Design

[a]Subjects were dispensed open-label rimegepant 75 mg in bottles containing 30 tablets; a maximum of 1 tablet per calendar day was permitted



[a]Subjects treated with rimegepant (i.e., safety population)

- Subjects were instructed to self-administer oral rimegepant 75 mg up to once daily as needed (PRN) to treat attacks of any pain intensity for 52 weeks
- Subjects were enrolled into different groups for analysis based on migraine attack frequency: 2 to 8 moderate or severe attacks per month (PRN 2-8) or 9-14 moderate or severe attacks per month (PRN 9-14)
- A 12-week scheduled every other day dosing group was also enrolled; however, this analysis focuses on the 52-week PRN dosing groups to better understand outcomes with as needed acute treatment with rimegepant

Subjects

- Aged ≥18 years, with ≥1-year history of migraine with or without aura
- Two to 14 moderate or severe monthly migraine attacks during the 3 months prior to the screening visit
- If using preventive medication, stable dose for ≥3 months

Methods *cont.*

Assessments

- Preference of Medication: a brief scale used to capture subjects' perception and preference regarding rimegepant compared with previous medications to treat their attacks; an electronic diary was used to evaluate preference of medication
- Satisfaction with Medication: a brief questionnaire used to capture subjects' level of satisfaction with rimegepant to treat their migraine attacks; an electronic diary was used to evaluate satisfaction with medication
- CGI-C: a brief observer-rated scale used to rate subject total improvement since study entry; the CGI-C was administered by the investigator (or a trained designee) and was completed on a paper form at the site
- In this post hoc analysis, preference of medication, satisfaction with medication, and CGI-C were analyzed in subjects with a history of treatment failure with 1 or ≥2 triptans

Statistical Analysis

- Outcome measures of preference of medication, satisfaction with medication, and CGI-C are based on subjects with data at the Week 24 and Week 52 visits and are presented as percentages with 2-sided Agresti-Coull 95% CIs
- Triptan treatment failure was defined as a self-reported history of triptan discontinuation due to inadequate efficacy or tolerability, or both, and included any medication in the triptan class

Results

Subjects

- Of the 1514 treated subjects in the PRN groups combined, 459 (30.3%) had a history of treatment failure with 1 triptan and 219 (14.5%) had failed ≥2 triptans
- Across all routes of administration, the most commonly failed triptans in both triptan failure subgroups were sumatriptan and rizatriptan
- Demographics and migraine history of the subgroups are shown in Table 1

Table 1. Baseline Demographics and Migraine History by History of Triptan Treatment Failure

	History of Treatment Failure With			
	1 Triptan		≥2 Triptans	
	PRN 2-8 n=320	PRN 9-14 n=139	PRN 2-8 n=138	PRN 9-14 n=81
DEMOGRAPHICS				
Age, years, mean (SD)	44.2 (11.4)	42.9 (11.0)	47.8 (11.1)	45.5 (12.9)
Sex, n (%)				
Female	296 (92.5)	132 (95.0)	125 (90.6)	73 (90.1)
Male	24 (7.5)	7 (5.0)	13 (9.4)	8 (9.9)
Race, n (%)				
White	266 (83.1)	117 (84.2)	123 (89.1)	75 (92.6)
Black or African American	42 (13.1)	15 (10.8)	9 (6.5)	4 (4.9)
Other[a]	12 (3.8)	7 (5.0)	6 (4.3)	2 (2.5)
MIGRAINE HISTORY				
Time since migraine onset, years, mean (SD)	24.3 (12.3)	23.7 (11.4)	26.9 (13.1)	27.9 (13.5)
Moderate-severe attacks/month,[b] mean (SD)	4.9 (1.9)	10.7 (1.6)	5.1 (1.8)	11.2 (1.7)
Duration of untreated attacks,[b] hours, mean (SD)	38.1 (23.1)	37.6 (21.9)	35.2 (22.3)	40.6 (23.0)
Primary migraine type[b]				
Without aura	207 (64.7)	86 (61.9)	89 (64.5)	52 (64.2)
With aura	113 (35.3)	53 (38.1)	49 (35.5)	29 (35.8)
Preventive medication use, n (%)	55 (17.2)	27 (19.4)	32 (23.2)	19 (23.5)

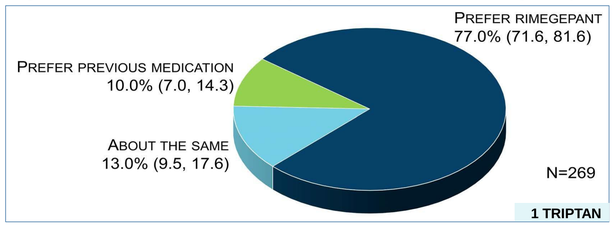
[a]Includes American Indian or Alaskan native, Asian, Hawaiian native or other Pacific Islander, or subjects of multiple races.
[b]Historical.

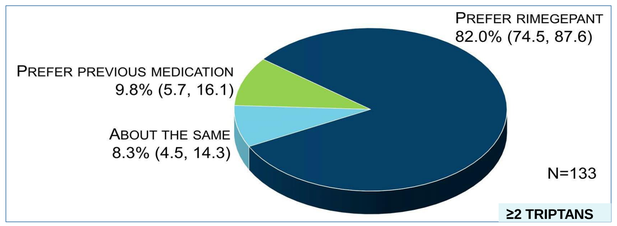
Results *cont.*

Preference of Medication

- At Week 24, 75.2% of subjects with a history of 1 triptan treatment failure (n=318) and 81.7% of those with a history of ≥2 triptan treatment failures (n=153) preferred rimegepant to their previous migraine treatments
- Results at Week 52 are shown in Figure 2

Figure 2. Preference for Rimegepant at Week 52 Among Subjects With a History of Triptan Treatment Failure

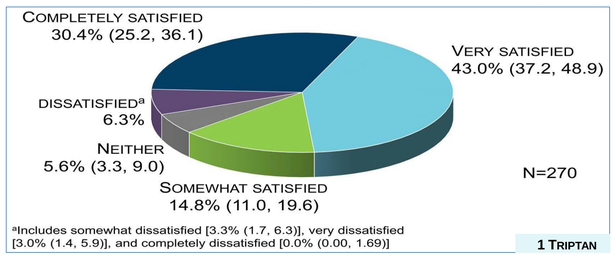




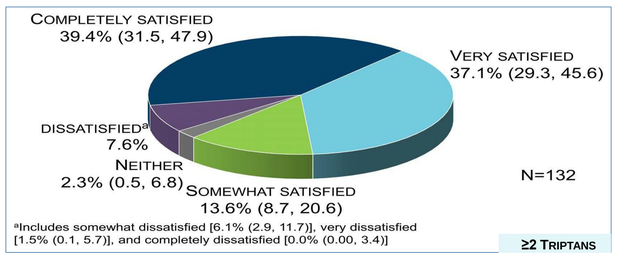
Satisfaction With Medication

- At Week 24, 89.0% of subjects with a history of 1 triptan treatment failure (n=317) and 90.2% of those with a history of ≥2 triptan treatment failures (n=153) were satisfied with rimegepant
- Results at Week 52 are shown in Figure 3

Figure 3. Satisfaction With Rimegepant at Week 52 Among Subjects With a History of Triptan Treatment Failure



[a]Includes somewhat dissatisfied [3.3% (1.7, 6.3)], very dissatisfied [3.0% (1.4, 5.9)], and completely dissatisfied [0.0% (0.00, 1.69)]

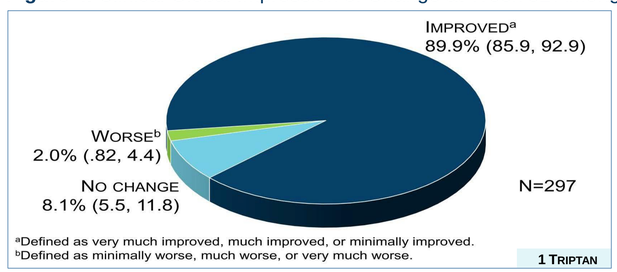


[a]Includes somewhat dissatisfied [6.1% (2.9, 11.7)], very dissatisfied [1.5% (0.1, 5.7)], and completely dissatisfied [0.0% (0.00, 3.4)]

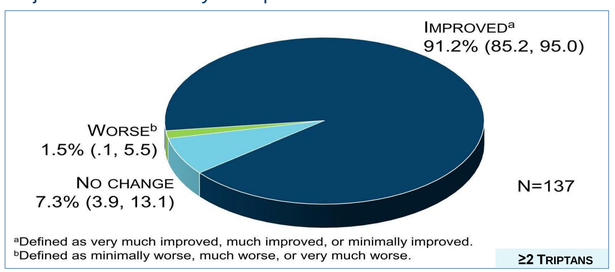
Clinical Global Impression of Change

- At Week 24, 87.6% of subjects with a history of 1 triptan treatment failure (n=363) and 89.2% of those with a history of ≥2 triptan treatment failures (n=176) were considered improved since study entry
- Results at Week 52 are shown in Figure 4

Figure 4. Clinical Global Impression of Change at Week 52 Among Subjects With a History of Triptan Treatment Failure



[a]Defined as very much improved, much improved, or minimally improved.
[b]Defined as minimally worse, much worse, or very much worse.



[a]Defined as very much improved, much improved, or minimally improved.
[b]Defined as minimally worse, much worse, or very much worse.

Conclusions

- Over 52 weeks of acute treatment with oral rimegepant, more than 75% of subjects with a history of triptan treatment failure preferred rimegepant to prior acute treatments for migraine and 9 in 10 subjects experienced clinical improvement

References: 1. Lipton R et al. *Headache*. 2018;58:1336-1337. [Poster #PS123LB]. 2. Lipton RB et al. *N Engl J Med*. 2019;381(2):142-149. 3. Croop R et al. *Lancet*. 2019;394(10200):737-745. 4. Marcus R et al. *Cephalalgia*. 2014;34(2):114-125. 5. Croop R et al. *Lancet*. 2021;397(10268):51-60.

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