# Sustained Efficacy of Rimegepant for the Acute Treatment of Migraine in Adults From China and South Korea

**DISCLOSURES:** Shengyuan Yu has no conflicts of interest. Yanhui Sun, Yu Liu, Qian Zhao, and Yunjun Zou are employees of Pfizer and own stock in Pfizer. Zhihong Lu was an employee of Pfizer and owns stock in Pfizer.

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## INTRODUCTION

- Approximately 151.6 million people in China have migraine.[1]
- There is a significant unmet need for safe and effective therapies for the acute treatment of migraine in China.[1]
- Rimegepant orally disintegrating tablet (ODT), an oral small-molecule calcitonin gene-related peptide receptor antagonist, is indicated for acute treatment of migraine and for preventive treatment of episodic migraine in the United States, European Union, United Kingdom, and other regions.[2,3]
- A randomized, placebo-controlled trial in adults living in China or South Korea (NCT04574362) demonstrated that acute treatment of migraine with a single dose of rimegepant 75 mg ODT improved pain and other symptoms of migraine.[4]
  - Rimegepant was superior to placebo on the co-primary endpoints of freedom from pain and freedom from the most bothersome symptom (MBS) at 2 h post dose.
  - Rimegepant was also superior to placebo on all key secondary efficacy endpoints, including pain relief at 2 h post dose, normal function at 2 h post dose, use of rescue medication within 24 h post dose, and sustained freedom from pain from 2–24 and 2–48 h post dose.

## OBJECTIVE

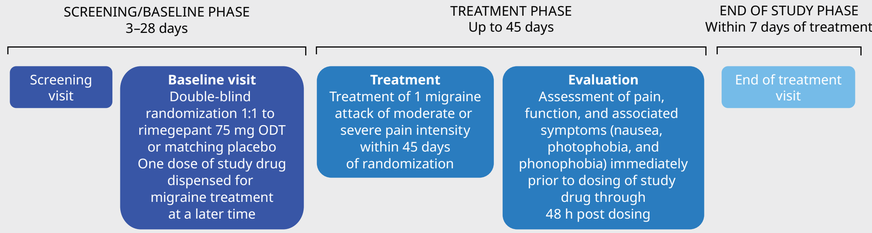
- This study further characterized the ability of rimegepant to provide sustained (up to 48 h post dose) efficacy in adults living in China or South Korea, based on analysis of additional prespecified secondary endpoints of study NCT04574362.

## METHODS

### PARTICIPANTS

- Participants were aged ≥18 years with a ≥1 year history of migraine (with or without aura), 2–8 moderate or severe migraine attacks per month, and <15 headache days per month during the 3 months before screening.
- Participants on preventive migraine medication were permitted to remain on preventive therapy provided dosing was stable for ≥3 months prior to screening.

**Figure 1: Study design**




ODT=orally disintegrating tablet

### TREATMENT

- Participants were randomized to rimegepant 75 mg ODT or matching placebo and provided a single dose of study medication to self-administer to treat a migraine attack of moderate or severe pain intensity within 45 days (**Figure 1**).
- Rescue medication (aspirin, ibuprofen, acetaminophen up to 1000 mg/day, NSAIDs, antiemetics, or baclofen) was allowed 2 h after administration of study medication and standard-of-care migraine treatments were allowed after 48 h.

### ENDPOINTS AND ANALYSIS

- Endpoints included the proportion of participants with sustained (2–24 and 2–48 h post dose) freedom from pain, sustained freedom from MBS, sustained pain relief, and sustained normal function.
- Treatments were compared (rimegepant vs placebo) using Mantel–Haenszel risk estimation.
  - Freedom from pain endpoints were key secondary endpoints with multiplicity controlled using the Hochberg procedure; other endpoints were exploratory and P values are nominal.
- Analyses were done in the modified intent-to-treat (mITT) population, which included all randomized participants who took study therapy, had a migraine of moderate or severe intensity at the time of treatment, and provided ≥1 post-treatment efficacy data point.

## RESULTS

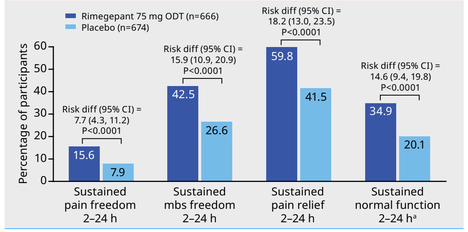
### PARTICIPANTS

- 1340 participants were included in the mITT population (rimegepant, n=666; placebo, n=674).
- Participant demographics were comparable across treatment groups (**Table**).

### SUSTAINED EFFICACY

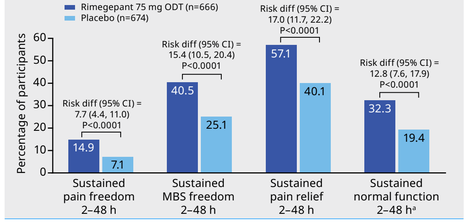
- Response rates for rimegepant were greater than placebo for sustained efficacy endpoints from 2–24 h (**Figure 2**).
  - Rate of freedom from pain was 15.6% for rimegepant and 7.9% for placebo (P<0.0001).
  - Rate of freedom from MBS was 42.5% for rimegepant and 26.6% for placebo (P<0.0001).
  - Rate of pain relief was 59.8% for rimegepant and 41.5% for placebo (P<0.0001).
  - Rate of normal function was 34.9% for rimegepant and 20.1% for placebo (P<0.0001).
- Response rates for rimegepant were also greater than placebo for sustained efficacy endpoints from 2–48 h (**Figure 3**).
  - Rate of freedom from pain was 14.9% for rimegepant and 7.1% for placebo (P<0.0001).
  - Rate of freedom from MBS was 40.5% for rimegepant and 25.1% for placebo (P<0.0001).
  - Rate of pain relief was 57.1% for rimegepant and 40.1% for placebo (P<0.0001).
  - Rate of normal function was 32.3% for rimegepant and 19.4% for placebo (P<0.0001).

**Figure 2: Summary of sustained (2–24 h post dose) endpoints in the mITT population**




Risk difference calculated from Mantel–Haenszel test, stratified by use of prophylactic medication and country. P value calculated from Cochran–Mantel–Haenszel test, stratified by use of prophylactic medication and country. Freedom from pain was a key secondary endpoint with multiplicity controlled using the Hochberg procedure; other endpoints were exploratory and P values are nominal.
[a] Based on those with any level of disability at baseline (rimegepant, n=545; placebo, n=551).
diff=difference; MBS=most bothersome symptom; mITT=modified intent-to-treat; ODT=orally disintegrating tablet

**Figure 3: Summary of sustained (2–48 h post dose) endpoints in the mITT population**




Risk difference calculated from Mantel–Haenszel test, stratified by use of prophylactic medication and country. P value calculated from Cochran–Mantel–Haenszel test, stratified by use of prophylactic medication and country. Freedom from pain was a key secondary endpoint with multiplicity controlled using the Hochberg procedure; other endpoints were exploratory and P values are nominal.
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**Table: Demographics for the mITT population**

| | Rimegepant 75 mg ODT n=666 | Placebo n=674 |
|---|---|---|
| Age, mean (SD), y | 37.8 (10.2) | 37.7 (10.7) |
| Gender, n (%) | | |
| Female | 525 (78.8) | 563 (83.5) |
| Male | 141 (21.2) | 111 (16.5) |
| Country, n (%) | | |
| China | 537 (80.6) | 537 (79.7) |
| South Korea | 129 (19.4) | 137 (20.3) |
| BMI, mean (SD), kg/m$^2$ | 23.00 (3.58)[a] | 22.99 (3.40) |
| Duration of diagnosis, mean (SD), y | 11.0 (8.7) | 11.4 (9.3) |
| Took preventive migraine medication, n (%) | 50 (7.5) | 48 (7.1) |
| Number of moderate or severe migraines per month, mean (SD) | 3.66 (1.41) | 3.62 (1.38) |
| Duration of untreated migraine attacks, mean (SD), h | 19.76 (15.59) | 20.28 (15.49) |
| Primary migraine type, n (%) | | |
| Without aura | 596 (89.5) | 606 (89.9) |
| With aura | 70 (10.5) | 68 (10.1) |

[a] n=665.
BMI=body mass index; mITT=modified intent-to-treat; ODT=orally disintegrating tablet

## CONCLUSION

- A single dose of rimegepant 75 mg ODT demonstrated sustained efficacy over 48 h for acute treatment of migraine in adults from China or South Korea.

### REFERENCES

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### ACKNOWLEDGMENTS

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