# Long-term Safety Study of Rimegepant in Pediatric Subjects for the Acute Treatment of Migraine

Status: RECRUITING

## Eligibility Criteria

Sex: ALL
Age: 6 years to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. History of migraine (with or without aura) for ≥ 6 months before Screening.
2. History of 1 to 8 moderate or severe attacks per month during the 2 months prior to screening.
3. 1 or more migraine days requiring treatment during the Observation Phase.
4. Prophylactic migraine medication is permitted if the dose has been stable for at least 12 weeks prior to the Screening Visit.
5. Ability to distinguish between migraine and other types of headaches.
6. Weight > 15 kg. For EU countries only: Participants 12 to < 18 years of age must have a body weight of >25kg.
7. Adequate venous access for blood sampling.
8. Male and female participants 6 to < 18 years of age (participants must not reach their 18th birthday on or before the Baseline visit).

Exclusion Criteria:

1. History of cluster headache or hemiplegic migraine headache.
2. Confounding and clinically significant pain syndrome.
3. Current uncontrolled and/or untreated psychiatric condition for a minimum of 6 months prior to the Screening Visit (lifetime history of psychosis and/or mania are excluded).
4. History of suicidal behavior or at risk of self-harm/harm to others.
5. History of major psychiatric disorder.
6. Current diagnosis or history of substance abuse
7. Reported current use of or tested positive at Screening for drugs of abuse.

## Conditions & Interventions

Interventions:
DRUG: Rimegepant (PF-07899801)
Conditions:
Acute Treatment of Migraine
Keywords:
Long-term safety, acute treatment, migraine, phonophobia, photophobia, nausea, pediatric, children, adolescent

## More Information

Description:
The purpose of this study is to test the long-term safety of rimegepant in the acute treatment of migraine in children and adolescents (≥ 6 to \< 18 years of age).

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