Efficacy and Safety Study of Rimegepant for the Preventative Treatment of Migraine in Pediatric Subjects

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. Subject has at least a 6 month history of migraine (with or without aura) and including the following:
    1. 14 or less headache days per month during the 3 month period prior to the Screening Visit
    2. 6 or more migraine days during the Observation Period
    3. 14 or less headache days during the Observation Period
    4. Pediatric Migraine Disability Assessment Scale (PedMIDAS) Disability Score of >10 to ≤50, indicating mild (score of 11 to 30) or moderate (score of 31 to 50) disruption in daily activities, as assessed at the Baseline (Randomization) Visit
    5. Ability to verbally distinguish migraine attacks from tension/cluster or other types of headaches
    6. Migraine attacks, on average, lasting 4 - 72 hours if untreated
    7. Subjects on prophylactic migraine medication are permitted to remain on therapy if the dose has been stable for at least 3 months (12 weeks) prior to the Screening Phase, and the dose is not expected to change during the course of the study. 2) Male and female subjects ≥ 6 to <18 years; subjects must be less than 18 at the time of signing assent / consent.

    3)Subjects must have a weight of ≥40 kg (child cohort requirement ≥15 kg) at the Screening Visit.

Exclusion Criteria:

1. Subjects with a history of basilar migraine, cluster headaches, or hemiplegic migraine
2. The subject has a continuous migraine (defined as an unrelenting headache) within 1 month prior to Screening Visit.
3. The subject has a history or diagnosis of complications of migraine
4. The subject has a confounding and clinically significant pain syndrome that may interfere with the subject's ability to participate in this study.
5. The subject has any current psychiatric condition that is uncontrolled and/or untreated for a minimum of 6 months prior to the Screening Visit. Subjects with a lifetime history of psychosis and/or mania are excluded.
6. History of suicidal behavior or the subject is at risk of self-harm or harm to others.
7. History of major psychiatric disorder.
8. The subject has a current diagnosis or history of substance abuse
9. The subject has a history of moderate or severe head trauma or other neurological disorder (including seizure disorder) or systemic medical disease that is, in the investigator's opinion, likely to affect central nervous system functioning.

Conditions & Interventions

Interventions:
DRUG: Rimegepant, DRUG: Placebo
Conditions:
Migraine
Keywords:
Migraine, Migraine prevention, Phonophobia, Photophobia, Nausea, Pediatric migraine, Adolescent migraine

More Information

Description:
The purpose of this study is to compare the efficacy and safety of rimegepant to placebo as a preventative treatment for migraine in children and adolescents ≥ 6 to \<18 years with episodic migraine.

Contact(s): Michelle Shin - michelle.shin@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE3
IRB Number:
System ID: NCT05156398