Randomized Study in Children and Adolescents With Migraine: Acute Treatment

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 according to the IHS Classification ICHD-319 specifications for pediatric migraine. History may be verified using both medical records and recall by the participant and/or participant's parent(s)/legal representative(s).
2. History of 1 to 8 moderate or severe attacks per month during the 2 months prior to enrollment, with attacks lasting > 3 hours without treatment, and attacks occurring at intervals > 24 hours.
3. Prophylactic migraine medication are permitted if the dose has been stable for at least 12 weeks prior to the Baseline Visit, and the dose is not expected to change during the course of the study.
    1. Participants may remain on one (1) medication with possible migraine prophylactic effects, excluding CGRP antagonists [biologic or small molecule], during the treatment phases.
    2. Concomitant use of a CGRP antagonist, such as erenumab or fremanezumab, is prohibited.
    3. Previously discontinued prophylactic migraine medication must have done so at least 90 days prior to the Screening Visit.
4. Verbally distinguish between migraine and other types of headaches.
5. Participants must have a weight > 40 kg at the Screening Visit.
6. Adequate venous access for blood sampling.
7. Male and female participants ≥ 6 to < 18 years of age (participants must not reach their 18th birthday during the study).

Exclusion Criteria:

1. History of cluster headache or hemiplegic migraine headache.
2. Confounding and clinically significant pain syndrome that may interfere with the participant's ability to participate in this study.
3. Current psychiatric condition that is uncontrolled and/or untreated for a minimum of 6 months prior to the Screening Visit. Participants with a lifetime history of psychosis and/or mania.
4. History of suicidal behavior or major psychiatric disorder.
5. Current diagnosis or history of substance abuse; positive drug test at Screening.
6. History of moderate or severe head trauma or other neurological disorder (including seizure disorder) or systemic medical disease that is likely to affect central nervous system functioning.
7. Recent or planned surgery, requiring general anesthesia, <8 weeks prior to the Screening Visit.
8. Participant has had gastrointestinal surgery that interferes with physiological absorption and motility (i.e., gastric bypass, duodenectomy, or gastric banding).
9. Current diagnosis of viral hepatitis or a history of liver disease.
10. Conditions considered clinically relevant in the context of the study such as uncontrolled hypertension (high blood pressure), diabetes, a life-threatening allergy

Conditions & Interventions

Interventions:
DRUG: Rimegepant/BHV3000, DRUG: Matching placebo
Conditions:
Pediatric Migraine
Keywords:
Migraine, Acute treatment, Phonophobia, Photophobia, Nausea, Pediatric, Children, Adolescent, Pediatric Migraine

More Information

Description:
The purpose of this study is to test the safety and efficacy of BHV-3000 versus placebo in the acute treatment of moderate or severe migraine in children and adolescents.

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IRB Number:
System ID: NCT04649242

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