A Study to Assess the Adverse Events and Change in Disease Activity of Oral Atogepant Tablets in Pediatric Participants (6-17 Years of Age) With Episodic Migraine

NCT05711394

Status	RECRUITING
Phase	Phase 3
Sponsor	AbbVie
Enrollment	450 participants

Key Eligibility Criteria

Inclusion (4)

- Weight is \>= 20 kg (44 lbs) and \< 135 kg (298 lbs).
- History of episodic migraine with or without aura consistent with a diagnosis according to the International Classification of Headache Disorders (ICHD) -3 (2018) for at least 6 months.
- Participant has to have 4 to 14 migraine days and \< 15 headache days in the 28-day baseline period per eDiary.
- To be eligible for the PK substudy, participants must be 6 to 11 years of age (inclusive), with a history of migraine (consistent with a diagnosis according to the ICHD-3 \[2018\]) and per investigator judgment is appropriate to receive preventive treatment for migraine.

Exclusion (3)

- History of migraine brainstem aura, hemiplegic migraine, or retinal migraine as defined by ICHD-3 (2018).
- Have a current diagnosis of chronic migraine as defined by ICHD-3 (2018).
- Have a current diagnosis of new daily persistent headache, trigeminal autonomic cephalgia (e.g., cluster headache), or painful cranial neuropathy as defined by ICHD-3 (2018).

Locations (98 total)

Rehabilitation & Neurological Services /ID# 248517, Huntsville, Alabama, United States
The Center for Clinical Trials - Saraland /ID# 271604, Saraland, Alabama, United States
Preferred Research Partners /ID# 249729, Little Rock, Arkansas, United States
... and 95 more locations