

Study of Oral Atogepant to Assess Adverse Events and Change in Disease Activity in Adult Participants With Menstrual Migraine

NCT06806293

Status	RECRUITING
Phase	Phase 3
Sponsor	AbbVie
Enrollment	430 participants

Key Eligibility Criteria

Inclusion (5)

- History and eDiary confirmation have regular menstrual cycles within the range of 21 to 35 days in length (Note: menstrual cycle length is calculated as onset of menses until the day before the next onset of menses).
- History of migraine (with or without aura) according to the International Classification of Headache Disorders, 3rd Edition (ICHD-3) for \geq 12 months prior to Visit 1/Screening.
- Migraine onset before age 50 years.
- By history at Visit 1/Screening, participant meets ICHD-3 criteria for pure menstrual migraine with or without aura, or menstrually-related migraine with or without aura, i.e., in at least 2 out of 3 cycles, experiences migraine attacks starting during the PMP (Day -2 to Day +3 relative to menses onset) in the opinion of the investigator.
- Participant records 3 perimenstrual periods (PMP) in the eDiary during the screening period, and in at least 2 of 3 PMPs the participant experiences and records a migraine attack in the eDiary with at least 1 migraine day.

Exclusion (7)

- History of an average of 15 or more headache days per month during the 3 months prior to Visit 1/Screening per the investigator's judgment, or a current diagnosis of chronic migraine as defined by International Classification of Headache Disorders, 3rd Edition (ICHD-3).
 - An average of 15 or more headache days per month recorded in the eDiary during the screening period.
 - History of migraine with brainstem aura, hemiplegic migraine, or retinal migraine as defined by ICHD-3.
 - Current diagnosis of new persistent daily headache, trigeminal autonomic cephalalgia (e.g., cluster headache), or painful cranial neuropathy as defined by ICHD-3.
 - Required hospital/emergency room treatment for migraine attacks 3 or more times within 6 months prior to Visit 1/Screening.
- ... and 2 more (see full listing online)

Locations (95 total)

Chinese PLA General Hospital /ID# 267141, Beijing, Beijing Municipality, China
Nanfang Hospital - Southern Medical University /ID# 268510, Guangzhou, Guangdong, China
Hebei General Hospital /ID# 267663, Shijiazhuang, Hebei, China
... and 92 more locations