A Study to Evaluate the Safety and Efficacy of JZP926 Capsule for the Treatment of Juvenile Myoclonic Epilepsy

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 10 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply:

1. Is ≥ 10 years of age at the time of screening.
2. Has a diagnosis of JME per ILAE criteria as specified in the protocol.
3. Has at least 4 myoclonic seizure days per 28 days historical seizure frequency.

Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

1. Presence of seizure types other than GTC, myoclonic, and absence seizures.
2. If historical MRI has been performed, participant's MRI reveals a cause of epilepsy other than JME.
3. Has a concurrent, confirmed diagnosis of non-epileptic seizures or events that can confound the assessment of the efficacy measures, in the opinion of the investigator.
4. The etiology of the participant's seizures is a progressive neurologic disease.
5. Has clinically unstable or progressive epilepsy.
6. Has clinically significant unstable medical condition(s), other than epilepsy, including unstable psychiatric disorders.
7. Has a history of status epilepticus in the 3 months prior to screening.
8. History of suicidal behavior, current suicidal risk as determined from history, or presence of active suicidal ideation as indicated by a positive response to Item 4 or Item 5 on the C-SSRS or is considered at risk of suicide or self-harm based on the clinical judgement of the investigator following interview with the participant and/or caregiver.
9. Has known or suspected hypersensitivity to cannabinoids or any of the excipients of the study intervention.
10. Is currently treated with Epidiolex or recently received treatment with Epidiolex within 28 days prior to screening.
11. Has a body weight < 20 kg or > 150 kg.
12. Is currently using or has used recreational or medicinal cannabis, cannabinoid/CBD based medications, products, or supplements (botanical or synthetic) within 28 days prior to screening.
13. Is unwilling or unable to abstain from recreational or medicinal cannabis, cannabinoid/CBD based medications, products, or supplements (botanical or synthetic) for the duration of the study.

Conditions & Interventions

Interventions:
DRUG: JZP926 capsule, DRUG: Placebo
Conditions:
Juvenile Myoclonic Epilepsy
Keywords:
Juvenile myoclonic epilepsy, JME, JZP926 capsule

More Information

Description:
This study is being conducted to evaluate the safety and efficacy of JZP926 capsule in participants with Juvenile Myoclonic Epilepsy (JME).

Contact(s): Clinical Trial Disclosure & Transparency - ClinicalTrialDisclosure@JazzPharma.com
Phase: PHASE2
System ID: NCT07723963

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