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A Study to Assess the Efficacy, Safety and Pharmacokinetics of EYU688 in Patients With Dengue Fever

Last Update: May 13, 2025
A Randomized, Participant- and Investigator-blinded, Placebo-controlled, Parallel Group Study to Assess the Efficacy, Safety and Pharmacokinetics of EYU688 in Patients With Dengue Fever
ClinicalTrials.gov Identifier:
NCT06006559
Novartis Reference Number:CEYU688A12201
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

The purpose of this study is to characterize the effect on dengue viral load, fever clearance time as well as on clinical signs and symptoms with the treatment of EYU688 compared with placebo in patients with dengue fever. This is a randomized, participant- and investigator- blinded, placebo-controlled study to investigate the efficacy and safety of EYU688 administered orally in patients with dengue fever.

Due to the different PK sampling schedules applied, the study consists of two cohorts run in parallel (intensive PK \[cohort 1\] and sparse PK sampling \[cohort 2\]).

Condition
Dengue
Phase
Phase2
Overall Status
Recruiting
Number of Participants
108
Start Date
Feb 20, 2024
Completion Date
Feb 27, 2026
Gender
All
Age(s)
18 Years - 60 Years (Adult)

Interventions

Drug

EYU688

EYU688 administered by oral route
Drug

Placebo

Matching placebo administered orally as capsules

Eligibility Criteria

Inclusion Criteria:

* Male or female, 18 - 60 years old (inclusive).
* History or presence of fever (≥ 38°C). At least one of the following criteria indicating dengue infection:
* Nausea or vomiting.
* Presence of rash, aches or pains including headache, muscle or joint pain.
* Onset of fever ≤ 48 hours prior to treatment start.
* Positive test on dengue fever.

Exclusion Criteria:

* Participants with any of abnormalities of clinical laboratory parameters.
* Usage of any anticoagulant drugs.
* Current significant medical conditions or illness that the investigator considers should exclude the participants, especially those that require continuation of other medications likely to have an interaction with the study drug.
* Pregnant or nursing (lactating) women.
* Clinical signs and symptoms for severe dengue according to Dengue Guideline (WHO 2009) at screening.
* Participants with any of the following abnormalities of clinical laboratory parameters at screening:

* Hemoglobin \<12.0 g/dL in males; \<11.0 g/dL in females
* Hematocrit \>52 % in males; \>46 % in females
* Absolute neutrophil count \<1500/µL
* Platelet count \<80,000/mm3
* Creatinine \>165 µmol/L in males; \>130 µmol/L in females
* Serum creatine kinase \> 600 U/L
* ALT, AST levels more than 1.5X upper limit of normal (ULN)
* Total bilirubin \>24 µmol/L
* Usage of PPIs (proton pump inhibitor) which could affect absorption of EYU688 due to stomach pH value increase up to 48 hours prior to screening.
* Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception during dosing and for 4 days after stopping of investigational drug.
* History or long-QT syndrome, or clinically significant ECG abnormalities, or any of the following ECG abnormalities at screening:

* QTcF \> 450 msec (males)

* QTcF \> 460 msec (females)

Other protocol-defined inclusion/exclusion criteria may apply.

Brazil

Novartis Investigative Site

Recruiting

Sorocaba,SP,18040-425,Brazil

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Recruiting

Manaus,AM,69040-000,Brazil

Novartis Investigative Site

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06006559*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT06006559
2. #trial-eligibility
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