Efficacy, Safety and Tolerability of KLU156 in Adults and Children ≥ 5 kg Body Weight With Uncomplicated P. Falciparum Malaria

Last Update: Apr 22, 2025

A Randomized, Open-label, Multicenter Study to Compare Efficacy, Safety and Tolerability of KLU156 With Coartem® in the Treatment of Uncomplicated Plasmodium Falciparum Malaria in Adults and Children ≥ 5 kg Body Weight Followed by an Extension Phase With Repeated KLU156 Treatment

ClinicalTrials.gov Identifier:
NCT05842954

Novartis Reference Number:CKLU156A12301

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

This study aims to confirm the efficacy, safety and tolerability of KLU156, a fixed dose combination of ganaplacide (KAF156) and a solid dispersion formulation of lumefantrine (lumefantrine-SDF), when administered once daily for three days in adults and children ≥ 5 kg body weight and ≥ 2 months of age suffering from uncomplicated P. falciparum malaria (with or without other Plasmodium spp. co-infection).

In the Extension phase, the safety, tolerability and efficacy of repeated treatment with KLU156 will be assessed for a maximum of two years in patients who did not experience early treatment failure (ETF), who did not experience any study treatment-related SAE (Serious Adverse Event) previously and who gave informed consent to participate in the Extension phase. The purpose of this study is to confirm the efficacy, safety and tolerability of KLU156 in patients with uncomplicated P. falciparum malaria (with or without other Plasmodium spp. co-infection) by demonstrating that KLU156 is non-inferior to Coartem.

* The study duration will be 43 days (Core phase) plus 24 months (Extension phase).
* The treatment duration will be 3 days for each malaria episode.
* The visit frequency will be Days 1-3 (hospitalized) and 5 follow-up visits (Days 4, 8, 22, 29 and 43) in the Core phase and Days 1-3 (hospitalized) and 3 follow-up visits (Days 4, 8 and 29) in the Extension phase.

Condition
Uncomplicated Plasmodium Falciparum Malaria
Phase
Phase3
Overall Status
Recruiting
Number of Participants
1500

Start Date
Mar 07, 2024
Completion Date
Aug 11, 2027
Gender
All
Age(s)
2 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

Coartem

Oral use. Dosing will be selected based on patient's body weight as per product's label.
Drug

KLU156

Oral use. KLU156 (400/480 mg) is the dose for patients with a bodyweight ≥ 35kg. Patients \

Eligibility Criteria

Key Inclusion criteria (Core phase)

1. Male or female patients ≥ 5 kg of body weight and ≥ 2 months of age
2. Microscopically confirmed diagnosis of uncomplicated P. falciparum malaria with an asexual P. falciparum parasitemia ≥ 1,000 and ≤ 200,000 parasites/µL at the time of pre-screening with or without other Plasmodium spp. co-infection.
3. Axillary temperature ≥ 37.5 ºC or oral temperature ≥ 38.0 ºC or tympanic/rectal temperature ≥ 38.5 ºC; or history of fever during the previous 24 hours (at least documented verbally)
4. Negative pregnancy test for patients of childbearing potential
5. Signed informed consent must be obtained before any assessment is performed; for minors, signed informed consent must be obtained from parent/legal guardian. If the parent/legal guardian is unable to read and write, then a witnessed consent according to local ethical standards is permitted. Patients who are capable of providing assent, must provide it along with parent/legal guardian consent or as per local ethical standards
6. The patient and/or their parent/legal guardian is able to understand and comply with protocol requirements, instructions and protocol-stated restrictions and is likely to complete the study as planned.

Key Exclusion criteria (Core phase)

1. Signs and symptoms of severe malaria according to WHO 2015 (World Health Organization)
2. Concurrent febrile illnesses (e.g., typhoid fever, known or suspected dengue fever, known COVID19)
3. Severe malnutrition. For patients ≥ 12 years: body mass index (BMI) \< 16.0. For children \< 12 years: less than 70% of median normalized WHO reference weight or very low mid-upper arm circumference (MUAC \< 115 mm)
4. Repeated vomiting (defined as \> 3 times in the 24 hours prior to start of screening) or severe diarrhea

(defined as \> 3 watery stools in the 24 hours prior to start of screening)
5. Clinically relevant abnormalities of electrolyte balance which require correction, e.g., hypokalemia, hypocalcemia or hypomagnesemia
6. Anemia (hemoglobin level \<7 g/dL)
7. Any surgical or medical condition which might significantly alter the absorption, distribution, metabolism, or excretion of drugs (e.g., Human immunodeficiency virus (HIV) patients on antiretroviral therapy (ART) or tuberculosis (TB) patients on treatment), or which may jeopardize the patient in case of participation in the study.
8. Any of the following:

* Aspartate Aminotransferase/ Alanine Aminotransferase (AST/ALT) \> 3 x the upper limit of normal (ULN), regardless of the level of total bilirubin
* Total bilirubin \> 3 x ULN
* Resting QT interval corrected by Fridericia's formula (QTcF) \> 450 ms at screening
9. Prior antimalarial therapy or antibiotics with antimalarial activity within minimum of their five plasma half-lives (or within 4 weeks of screening if half-life is unknown)
10. History or family history of long QT syndrome or sudden cardiac death, or any other clinical condition known to prolong the QTc interval, such as history of symptomatic cardiac arrhythmias, clinically relevant bradycardia or severe heart disease
11. Pregnant or nursing (lactating) patients.

Other protocol-defined inclusion/exclusion criteria may apply.

Burkina Faso

Novartis Investigative Site

Recruiting

Ouagadougou,11 bp 218,Burkina Faso

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Recruiting

Sabou,06 bp 10248,Burkina Faso

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Recruiting

Banfora,Burkina Faso

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Recruiting

Bobo Dioulasso,01,Burkina Faso

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Recruiting

Nanoro,Bp 18,Burkina Faso

Congo, The Democratic Republic of the

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Recruiting

Masi Manimba,Kwilu,Congo, The Democratic Republic of the

Côte D'Ivoire

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Recruiting

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Recruiting

Agboville,Bp 154,Côte D'Ivoire

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Recruiting

Azaguie,Bp 173,Côte D'Ivoire

Gabon

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Recruiting

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Recruiting

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