Platform Study to Evaluate the Efficacy and Safety of Anti-malarial Agents in Patients With Uncomplicated Plasmodium Falciparum Malaria

Last Update: Mar 28, 2025

A Multi-part, Multi-center PLATform Study to Assess the Efficacy, Safety, Tolerability and Pharmacokinetics of Anti-malarial Agents Administered as Monotherapy and/or Combination Therapy IN Patients With Uncomplicated Plasmodium Falciparum Malaria

ClinicalTrials.gov Identifier:

NCT05750628

Novartis Reference Number:CADPT13A12201

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

Platform study to evaluate the efficacy and safety of anti-malarial agents in patients with uncomplicated Plasmodium falciparum malaria The purpose of this platform study is to evaluate the parasiticidal effect and potential for cure with different anti-malarial agents administered as monotherapy and/or in combination therapy with other anti-malarial agents in adults, adolescents, and children with uncomplicated Plasmodium falciparum malaria. Additionally, the safety, tolerability, and pharmacokinetics of these anti-malarial agents will be evaluated for dose selection for future studies.

Condition

Uncomplicated Plasmodium Falciparum Malaria

Phase

Phase2

Overall Status

Recruiting

Number of Participants

327

Start Date

Jan 23, 2024

Completion Date

Jun 19, 2026

Gender

All

Age(s)

2 Years - 100 Years (Child, Adult, Older Adult)

Interventions

Drug

INE963

oral INE963
Drug

KAE609 (Cipargamin)

oral KAE609 (Cipargamin)
Drug

KLU156

oral sachet KLU156 (KAF156 + lumefantrine)
Drug

SoC (Coartem)

SoC (Coartem)

Eligibility Criteria

Inclusion Criteria:

1. Male and female patients ≥18 years of age for Part A, ≥12 years of age for Part B and 2 to \<12 years of age for Part C at screening.
2. Patients must have acute uncomplicated P. falciparum malaria mono infection at screening confirmed by a parasite count between 5,000 to 150,000 asexual parasite count/µl of blood for P. falciparum for Part A and between 1,000 to 150,000 asexual parasite count/µl of blood for Parts B and C.
3. Patients in Part A must weigh between 40 kg and 90 kg. Patients in Part B must weigh between 35 kg and 90 kg at screening. Patients in Part C must weigh at least 10 kg at screening.
4. Axillary temperature ≥ 37.5ºC or oral/tympanic/rectal temperature ≥ 38.0ºC; or history of fever during the previous 24 hours.

Exclusion Criteria:

1. Patients with signs and symptoms of severe/complicated malaria at screening or mixed Plasmodium infection (i.e., infection with more than one malaria species) at screening
2. Moderate to severe anemia, chronic hemoglobinopathy (Hemoglobin level \< 8 g/dL), or known chronic underlying disease such as sickle cell disease at screening
3. Known clinically significant liver disease (e.g., chronic hepatitis, liver cirrhosis (compensated or decompensated), history of hepatitis B or C, hepatitis A or B vaccination in the last 3 months, known gallbladder or bile duct disease, acute or chronic pancreatitis. Clinical or laboratory evidence of any of the following at screening:

* AST/ALT \> 3 x the upper limit of normal range (ULN), regardless of the level of total bilirubin
* AST/ALT \> 1.5 and ≤ 2 x ULN and total bilirubin is \> ULN
* Total bilirubin \> 2 x ULN, regardless of the level of AST/ALT

4. Any known/suspected immunosuppressive or immunodeficient condition, including human immunodeficiency virus (HIV) infection at screening.

5. Pregnant or nursing (lactating) women, women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using methods of effective contraception, and sexually active patients not willing to practice effective contraception.
6. History or current diagnosis of ECG abnormalities indicating significant risk of safety for patients participating in the study such as:

* Concomitant clinically significant cardiac arrhythmias, e.g., sustained ventricular tachycardia, and clinically significant second or third degree AV block without a pacemaker
* History of familial long QT syndrome or known family history of Torsades de Pointe.
* Resting heart rate (physical exam or 12 lead ECG) \< 50 bpm

Other protocol-defined inclusion/exclusion criteria may apply.

Burkina Faso

Novartis Investigative Site

Recruiting

Banfora,Burkina Faso

Novartis Investigative Site

Recruiting

Nanoro,Bp 18,Burkina Faso

Côte D'Ivoire

Novartis Investigative Site

Recruiting

Abidjan,13bp972,Côte D'Ivoire

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Recruiting

Azaguie,Bp 173,Côte D'Ivoire

Gabon

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Recruiting

Lambarene,Bp 242,Gabon

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Recruiting

Libreville,Bp 1437,Gabon

Ghana

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Recruiting

Navrango,Vwj6+8wf,Ghana

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Recruiting

Kintampo,92037,Ghana

Kenya

Novartis Investigative Site

Recruiting

Kisumu,40100,Kenya

Uganda

Novartis Investigative Site

Recruiting

Kampala,Uganda

Novartis Investigative Site

Recruiting

Tororo,10102,Uganda

Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct05750628*

List of links present in page

1. https://clinicaltrials.gov/ct2/show/NCT05750628
2. #trial-eligibility

3. tel:+41613241111
4. mailto:novartis.email@novartis.com