**ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt**
Release Date: July 24, 2026

**ClinicalTrials.gov ID: NCT05842954**

## Study Identification

| | |
|---|---|
| Unique Protocol ID: | CKLU156A12301 |
| Brief Title: | Efficacy, Safety and Tolerability of KLU156 in Adults and Children With Uncomplicated P. Falciparum Malaria ( KALUMA ) |
| Official Title: | 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 Followed by an Extension Phase With Repeated KLU156 Treatment |
| Secondary IDs: | 2022-002675-10 [EudraCT Number] |

## Study Status

| | |
|---|---|
| Record Verification: | July 2026 |
| Overall Status: | Completed |
| Study Start: | March 7, 2024 [Actual] |
| Primary Completion: | June 27, 2025 [Actual] |
| Study Completion: | November 25, 2025 [Actual] |

## Sponsor/Collaborators

| | |
|---|---|
| Sponsor: | Novartis Pharmaceuticals |
| Responsible Party: | Sponsor |
| Collaborators: | Medicines for Malaria Venture (MMV), EDCTP, WANECAM |

## Oversight

| | |
|---|---|
| U.S. FDA-regulated Drug: | No |

| | |
|---|---|
| U.S. FDA-regulated Device: | No |
| U.S. FDA IND/IDE: | No |
| Human Subjects Review: | Board Status: Approved<br>Approval Number: 816/CNES/BN/PMMF/2024<br>Board Name: Comité National d'Ethique de la Santé (CNES)<br>Board Affiliation: Ministère de la Santé Publique<br>Phone: + 243 99 84 19 8 16<br>Email: feli1munday@yahoo.fr<br>Address:<br><br>Immeuble PNMLS, 1er niveau, Local 5, Commune de Kasa-Vubu KINSHASA, République Démocratique du Congo |
| Data Monitoring: | Yes |

## Study Description

**Brief Summary:** This study aimed 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 ≥ 10 kg of body weight 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 was assessed for a maximum of approximately 18 months 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.

**Detailed Description:** The purpose of this study was 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 total study duration was up to approximately 20 months.
- The treatment duration was 3 days for each malaria episode.
- The visit frequency was 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.

This study had two different primary outcomes depending on the submission (US New Drug Application (NDA) or non-US submissions).

Protocol amendment 01 increased the minimum body weight requirement for study participation from ≥ 5 kg to ≥ 10 kg and revised the statistical analysis plan to exclude patients < 10 kg from the main analyses.

## Conditions

| | |
|---|---|
| Conditions: | Uncomplicated Plasmodium Falciparum Malaria |
| Keywords: | malaria<br>Plasmodium falciparum |

KLU156
Coartem
artemether
lumefantrine
ganaplacide

## Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Single (Outcomes Assessor)
The Novartis clinical trial team (CTT) was blinded to the identity of the treatment from the time of randomization until the database lock for the analysis of the Core phase. Prior to unblinding the data of the Core phase (for the Novartis CTT), at least three DMC reviews were planned to minimize risks in this vulnerable patient population:

1. Once the first 200 patients (across both treatment arms) in the Core phase were dosed and followed up to at least Day 22.
2. Once the first 750 patients (across both treatment arms) in the Core phase were dosed and followed up to at least Day 22.
3. Additional DMC reviews may have been conducted ad-hoc during the study, as deemed necessary.

All safety data from the Core phase as well as from the Extension phase that were available at these 2 scheduled timepoints were included in the DMC reviews. After the database lock of the Core phase, the CTT was unblinded.

Allocation: Randomized

Enrollment: 1720 [Actual]

## Arms and Interventions

| Arms | Assigned Interventions |
|---|---|
| Experimental: KLU156<br>KLU156 once daily (QD) for 3 days under fed conditions (light meal). | Drug: KLU156<br>Oral use. KLU156 (400/480 mg) was the dose for patients with a bodyweight ≥ 35kg. Patients < 35kg took a fraction of the dose according to weight group as defined in the protocol. |
| Active Comparator: Coartem<br>Coartem twice a day (BID) for 3 days under fed conditions. | Drug: Coartem<br>Oral use. Dosing was selected based on patient's body weight as per product's label. |
| Experimental: KLU156 (Participants with <10 kg Body Weight) | Drug: KLU156 |

| Arms | Assigned Interventions |
|---|---|
| KLU156 once daily (QD) for 3 days under fed conditions (light meal). | Oral use. KLU156 (400/480 mg) was the dose for patients with a bodyweight ≥ 35kg. Patients < 35kg took a fraction of the dose according to weight group as defined in the protocol. |
| Active Comparator: Coartem (Participants with <10 kg Body Weight)<br>Coartem twice a day (BID) for 3 days under fed conditions. | Drug: Coartem<br>Oral use. Dosing was selected based on patient's body weight as per product's label. |

## Outcome Measures

[See Results Section.]

## Eligibility

Minimum Age: 2 Months

Maximum Age: 100 Years

Sex: All

Gender Based: No

Accepts Healthy Volunteers: No

Criteria: Key Inclusion criteria (Core phase)

1. Male or female patients ≥ 10 kg of body weight.
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 was obtained before any assessment is performed; for minors, signed informed consent was obtained from parent/legal guardian. If the parent/legal guardian was unable to read and write, then a witnessed consent according to local ethical standards was permitted. Patients who were capable of providing assent, must have provided it along with parent/legal guardian consent or as per local ethical standards
6. The patient and/or their parent/legal guardian was able to understand and comply with protocol requirements, instructions and protocol-stated restrictions and was 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 required correction, e.g., hypokalemia, hypocalcemia or hypomagnesemia
6. Anemia (hemoglobin level <7 g/dL)
7. Any surgical or medical condition which might have significantly altered 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 have jeopardized 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 was 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.

## Contacts/Locations

Central Contact Person: Novartis Pharmaceuticals
Telephone: +41613241111
Email: Novartis.email@novartis.com

Central Contact Backup: Novartis Pharmaceuticals

Study Officials:

Locations: **India**
Novartis Investigative Site
Bhubaneswar, Odisha, India, 751003

**Kenya**
Novartis Investigative Site
Nairobi, Kenya, 00200

**Zambia**
Novartis Investigative Site
Ndola, Zambia, 71769

**Gabon**
Novartis Investigative Site
Lambarene, Gabon, BP 242

**Zambia**

Novartis Investigative Site
Nchelenge, Luapula, Zambia, 70100

**Tanzania**
Novartis Investigative Site
Tanga, Tanzania, 5004

Novartis Investigative Site
Korogwe Tanga, Tanzania

**Burkina Faso**
Novartis Investigative Site
Bobo Dioulasso, Burkina Faso, 01

**Côte d'Ivoire**
Novartis Investigative Site
Agboville, Côte d'Ivoire, BP 154

**Tanzania**
Novartis Investigative Site
Bagamoyo, Tanzania, 78373

**Kenya**
Novartis Investigative Site
Siaya, Kenya, 2300

**Rwanda**
Novartis Investigative Site
Kigali, Rwanda, BP 4560

**Burkina Faso**
Novartis Investigative Site
Sabou, Burkina Faso

Novartis Investigative Site
Banfora, Burkina Faso

**India**
Novartis Investigative Site
Jaipur, Rajasthan, India, 302017

**Gabon**
Novartis Investigative Site
Libreville, Gabon, BP 1437

**Rwanda**

Novartis Investigative Site
Kigali, Rwanda, 0000

**Niger**
Novartis Investigative Site
Niamey, Niger, 8003

**Rwanda**
Novartis Investigative Site
Rubavu, Rwanda

Novartis Investigative Site
Rusizi, Rwanda

**Burkina Faso**
Novartis Investigative Site
Ouagadougou, Burkina Faso, 11 BP 218

**Democratic Republic of the Congo**
Novartis Investigative Site
Kenge, Kwango, Democratic Republic of the Congo

Novartis Investigative Site
Masi Manimba, Kwilu, Democratic Republic of the Congo

Novartis Investigative Site
Kisantu, Kongo Central, Democratic Republic of the Congo

Novartis Investigative Site
Kimpese, Kongo Central, Democratic Republic of the Congo

**Côte d'Ivoire**
Novartis Investigative Site
Azaguie, Côte d'Ivoire, BP 173

**Kenya**
Novartis Investigative Site
Kombewa, Kenya, 40102

**Mali**
Novartis Investigative Site
Sotuba, Mali

**Uganda**
Novartis Investigative Site
Tororo, Uganda, 10102

**Ghana**
Novartis Investigative Site
Navrango, Ghana, VWJ6+8WF

Novartis Investigative Site
Kintampo, Ghana, 92037

**Burkina Faso**
Novartis Investigative Site
Nanoro, Burkina Faso, BP 18

**Democratic Republic of the Congo**
Novartis Investigative Site
Lubumbashi, Du Haut Katanga, Democratic Republic of the Congo, 7010

**Rwanda**
Novartis Investigative Site
Gicumbi, Northern Province, Rwanda, 00114

**India**
Novartis Investigative Site
Darjeeling, West Bengal, India, 734012

**Côte d'Ivoire**
Novartis Investigative Site
Abidjan, Côte d'Ivoire, 13BP972

Novartis Investigative Site
Abidjan, Côte d'Ivoire, 13BP972

## IPDSharing

Plan to Share IPD: Yes
Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent review panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations. This trial data availability is according to the criteria and process described on www.clinicalstudydatarequest.com.

Supporting Information:

Time Frame:
Access Criteria:
URL:

### References

Citations:

Links:

Available IPD/Information:

## Documents

Study Protocol
Document Date: May 19, 2025
Uploaded: 05/22/2026 04:30

Statistical Analysis Plan
Document Date: September 29, 2025
Uploaded: 05/22/2026 04:33

# Study Results

## Participant Flow

| | |
|---|---|
| Pre-assignment Details | Patients were screened at 35 centers in 13 countries across Sub-Saharan Africa and India. |

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |
| KLU156 (Participants With <10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With <10 kg Body Weight | Coartem twice a day (BID) for 3 days under fed conditions. |

Core Phase

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) | KLU156 (Participants With <10 kg Body Weight) | Coartem (Participants With <10 kg Body Weight |
|---|---|---|---|---|
| Started [1] | 836 | 832 | 24 | 28 |
| Safety Set | 830 | 831 | 24 | 27 |
| Modified Randomized Set (mRAS) [2] | 836 | 832 | 0 | 0 |
| Modified Safety Set [2] | 830 | 831 | 0 | 0 |
| Completed | 767 | 824 | 14 | 27 |
| Not Completed | 69 | 8 | 10 | 1 |
| Not Treated in Core | 6 | 1 | 0 | 1 |
| Adverse Event | 62 | 5 | 9 | 0 |
| Guardian Decision | 1 | 1 | 0 | 0 |
| Protocol Deviation | 0 | 1 | 0 | 0 |
| Technical Problems | 0 | 0 | 1 | 0 |

[1] Randomized

[2] Included patients with body weight ≥10 kg. Protocol amendment 01 increased the minimum body weight requirement for study participation from ≥ 5 kg to ≥ 10 kg and revised the statistical analysis plan to exclude patients < 10 kg from the main analyses.

Extension Phase

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) | KLU156 (Participants With <10 kg Body Weight) | Coartem (Participants With <10 kg Body Weight |
|---|---|---|---|---|
| Started [1] | 190 [1] | 203 [1] | 2 [1] | 0 [1] |
| Completed | 190 | 203 | 2 | 0 |
| Not Completed | 0 | 0 | 0 | 0 |

[1] In the extension phase, participants only received KLU156, as needed

# Baseline Characteristics

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |
| KLU156 (Participants With <10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With <10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Baseline Measures

| | | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) | KLU156 (Participants With <10 kg Body Weight) | Coartem (Participants With <10 kg Body Weight) | Total |
|---|---|---|---|---|---|---|
| Overall Number of Participants | | 836 | 832 | 24 | 27 | 1719 |
| **Age, Continuous**<br>Mean (Standard Deviation)<br>Unit of measure: years | Number Analyzed | 836 participants | 832 participants | 24 participants | 27 participants | 1719 participants |
| | | 12.13 (10.46) | 11.94 (9.91) | 1.60 (0.47) | 1.80 (0.60) | 11.73 (10.19) |
| **Age, Customized**<br>Measure Type: Count of Participants<br>Unit of measure: participants | Number Analyzed | 836 participants | 832 participants | 24 participants | 27 participants | 1719 participants |
| Infants and toddlers (28 days-23 months) | | 13 1.56% | 9 1.08% | 18 75% | 13 48.15% | 53 3.08% |
| Children (2-11 years) | | 506 60.53% | 515 61.9% | 6 25% | 14 51.85% | 1041 60.56% |
| Adolescents (12-17 years) | | 162 19.38% | 152 18.27% | 0 0% | 0 0% | 314 18.27% |

| | | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) | KLU156 (Participants With <10 kg Body Weight) | Coartem (Participants With <10 kg Body Weight) | Total |
|---|---|---|---|---|---|---|
| Adults (18-64 years) | | 152 18.18% | 155 18.63% | 0 0% | 0 0% | 307 17.86% |
| From 65-84 years | | 3 0.36% | 1 0.12% | 0 0% | 0 0% | 4 0.23% |
| **Sex: Female, Male** Measure Type: Count of Participants Unit of measure: participants | Number Analyzed | 836 participants | 832 participants | 24 participants | 27 participants | 1719 participants |
| | Female | 419 50.12% | 395 47.48% | 15 62.5% | 14 51.85% | 843 49.04% |
| | Male | 417 49.88% | 437 52.52% | 9 37.5% | 13 48.15% | 876 50.96% |
| **Race/Ethnicity, Customized** Measure Type: Count of Participants Unit of measure: participants | Number Analyzed | 836 participants | 832 participants | 24 participants | 27 participants | 1719 participants |
| Black or African American | | 816 97.61% | 813 97.72% | 24 100% | 27 100% | 1680 97.73% |
| Race Not Reported | | 19 2.27% | 19 2.28% | 0 0% | 0 0% | 38 2.21% |
| Race Unknown | | 1 0.12% | 0 0% | 0 0% | 0 0% | 1 0.06% |
| Not Hispanic or Latino | | 755 90.31% | 746 89.66% | 24 100% | 27 100% | 1552 90.29% |
| Ethnicity Not reported | | 81 9.69% | 86 10.34% | 0 0% | 0 0% | 167 9.71% |

## Outcome Measures

**1. Primary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: PCR-corrected Adequate Clinical and Parasitological Response (ACPR) at Day 29 |
| Measure Description | PCR-corrected Adequate Clinical and Parasitological Response (ACPR) at Day 29 is defined as the percentage of participants who are clinically well and have no recrudescence (reappearance of the original malaria infection) by 29 days after treatment, with PCR genotyping used to distinguish new infections from recrudescence. This primary outcome was applicable to the non-US submission. |
| Time Frame | Day 29 (i.e., 28 days post-first dose administration) |

Analysis Population Description

Observed principal stratum: a subset of the modified full analysis set (mFAS) including patients with a baseline parasite count of 1,000-200,000/µL who (a) took at least 80% of study medication and (b) did not take non-study treatment with antimalarial activity prior to Day 29, except as rescue therapy in case of recrudescence of parasites.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 657 | 686 |
| Core Phase: PCR-corrected Adequate Clinical and Parasitological Response (ACPR) at Day 29<br>Number (95% Confidence Interval)<br>Unit of measure: percentage of participants | 97.4 (95.9 to 98.5) | 94.0 (92.0 to 95.7) |

Statistical Analysis 1 for Core Phase: PCR-corrected Adequate Clinical and Parasitological Response (ACPR) at Day 29

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Group Selection | KLU156 (Participants With ≥10 kg Body Weight), Coartem (Participants With ≥10 kg Body Weight) |
| | Comments | [Not specified] |
| | Type of Statistical Test | Non-Inferiority |
| | Comments | Non-inferiority of KLU156 versus Coartem was concluded if the lower limit of the 2-sided 95% CI was above the pre-defined -5% non-inferiority margin. |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | |
| | Comments | [Not specified] |
| | Method | Other [Wilson uncorrected method] |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Risk Difference (RD) |
| | Estimated Value | 3.4 |
| | Confidence Interval | (2-Sided) 95%<br>1.2 to 5.6 |
| | Estimation Comments | [Not specified] |

**2. Primary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Uncorrected ACPR (US NDA Submission) at Day 29 |
| Measure Description | Uncorrected ACPR at Day 29 is defined as the percentage of participants who are clinically well and have no malaria parasite reappearance detected by Day 29 after treatment, without using parasite genotyping to distinguish new infections from recrudescence of the original infection. This primary outcome was applicable to US New Drug Application (NDA) submission. |
| Time Frame | Day 29 |

Analysis Population Description

mFAS (regardless of study treatment discontinuation or non-compliance). Patients with intake of non-study treatment with antimalarial activity were considered as non-responders.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 726 | 722 |
| Core Phase: Uncorrected ACPR (US NDA Submission) at Day 29<br>Number (95% Confidence Interval)<br>Unit of measure: percentage of participants | 85.3 (82.5 to 87.8) | 82.1 (79.1 to 84.9) |

Statistical Analysis 1 for Core Phase: Uncorrected ACPR (US NDA Submission) at Day 29

| | | |
|---|---|---|
| Statistical Analysis Overview | Comparison Group Selection | KLU156 (Participants With ≥10 kg Body Weight), Coartem (Participants With ≥10 kg Body Weight) |
| | Comments | [Not specified] |
| | Type of Statistical Test | Non-Inferiority |
| | Comments | Non-inferiority of KLU156 versus Coartem was concluded if the lower limit of the 2-sided 95% CI was above the pre-defined -7.5% non-inferiority margin. |

| | | |
|---|---|---|
| Statistical Test of Hypothesis | P-Value | |
| | Comments | [Not specified] |
| | Method | Other [Wilson uncorrected method] |
| | Comments | [Not specified] |

| | | |
|---|---|---|
| Method of Estimation | Estimation Parameter | Risk Difference (RD) |
| | Estimated Value | 3.1 |
| | Confidence Interval | (2-Sided) 95%<br>-0.7 to 6.9 |
| | Estimation Comments | [Not specified] |

**3. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: PCR-corrected ACPR at Days 22 and 43 |
| Measure Description | To confirm the efficacy of KLU156 by assessing PCR-corrected ACPR at additional time points. |
| Time Frame | Days 22 and 43 (i.e., 21 and 42 days post-first dose administration) |

Analysis Population Description

Observed principal stratum in mFAS. Data are reported for evaluable participants at timepoint.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|---|
| Overall Number of Participants Analyzed | | 664 | 713 |
| Core Phase: PCR-corrected ACPR at Days 22 and 43<br>Number (95% Confidence Interval)<br>Unit of measure: percentage of participants | [Not specified] | | |
| Day 22 n=664,713 | Number Analyzed | 664 participants | 713 participants |
| | | 98.9 (97.8 to 99.6) | 96.5 (94.9 to 97.7) |
| Day 43/End of Core Phase n=626,627 | Number Analyzed | 626 participants | 627 participants |
| | | 94.6 (92.5 to 96.2) | 91.7 (89.3 to 93.7) |

**4. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Uncorrected ACPR at Days 22 and 43 |
| Measure Description | To confirm the efficacy of KLU156 by assessing uncorrected ACPR at additional time points. |
| Time Frame | Days 22 and 43 (i.e., 21 and 42 days post-first dose administration) |

Analysis Population Description

mFAS. Data are reported for evaluable participants at timepoint.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 726 | 722 |
| Core Phase: Uncorrected ACPR at Days 22 and 43<br>Number (95% Confidence Interval)<br>Unit of measure: percentage of participants | | |
| Day 22 n=726,722 | 90.1 (87.7 to 92.2) | 92.1 (89.9 to 94.0) |
| Day 43/End of Core Phase n=726,722 | 74.4 (71.0 to 77.5) | 72.6 (69.2 to 75.8) |

**5. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Percentage of Participants With Recrudescence |
| Measure Description | Recrudescence is defined as appearance of asexual parasites after clearance of initial infection with a genotype identical to that of parasites present at baseline. Recrudescence had to be confirmed by PCR analysis. |
| Time Frame | Days 22, 29 and 43 |

Analysis Population Description

mFAS. Data are reported for evaluable participants at timepoint.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 667 | 711 |

| | | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|---|
| Core Phase: Percentage of Participants With Recrudescence<br>Measure Type: Number<br>Unit of measure: percentage of participants | [Not specified] | | |
| Day 8 to Day 22 n=667,711 | Number Analyzed | 667 participants | 711 participants |
| | | 0 | 0.8 |
| Day 23 to Day 29 n=658,680 | Number Analyzed | 658 participants | 680 participants |
| | | 0.4 | 2.2 |
| Day 30 to Day 43 n=626,615 | Number Analyzed | 626 participants | 615 participants |
| | | 1.9 | 0.8 |

**6. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Percentage of Participants With New Infection |
| Measure Description | New infection is defined as appearance of asexual parasites after clearance of initial infection with a genotype different from those parasites present at baseline. New infection had to be confirmed by PCR analysis. |
| Time Frame | Days 22, 29 and 43 |

Analysis Population Description

mFAS. Data are reported for evaluable participants at timepoint.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|---|
| Overall Number of Participants Analyzed | | 667 | 711 |
| Core Phase: Percentage of Participants With New Infection<br>Measure Type: Number<br>Unit of measure: percentage of participants | [Not specified] | | |
| Day 8 to Day 22 n=667,711 | Number Analyzed | 667 participants | 711 participants |
| | | 0.5 | 2.7 |
| Day 23 to Day 29 n=657,674 | Number Analyzed | 657 participants | 674 participants |
| | | 2.2 | 6.8 |
| Day 30 to Day 43 n=625,608 | Number Analyzed | 625 participants | 608 participants |
| | | 10.6 | 10.5 |

**7. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Fever Clearance Time |
| Measure Description | Fever clearance time is defined as time from the first dose until the first time the axillary body temperature decreased below and remained below 37.5°C axillary or 38.0°C oral/tympanic/rectal for at least a further 24 hours. |
| Time Frame | Up to Day 3 |

Analysis Population Description
mFAS

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 726 | 722 |
| Core Phase: Fever Clearance Time<br>Median (95% Confidence Interval)<br>Unit of measure: hours | 6.3 (6.0 to 11.6) | 11.9 (11.4 to 12.0) |

**8. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Parasite Clearance Time |
| Measure Description | Parasite clearance time is defined as time from the first dose until the first total and continued disappearance of asexual parasite forms which remained at least a further 48 hours. |
| Time Frame | Up to Day 3 |

Analysis Population Description
mFAS

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 726 | 722 |
| Core Phase: Parasite Clearance Time<br>Median (95% Confidence Interval)<br>Unit of measure: hours | 37.6 (36.2 to 46.9) | 36.0 (35.9 to 36.0) |

**9. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Gametocyte Clearance Time |
| Measure Description | To confirm the efficacy of KLU156 by assessing gametocyte clearance between the two treatment arms |
| Time Frame | Up to Day 3 |

Analysis Population Description
mFAS

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 726 | 722 |
| Core Phase: Gametocyte Clearance Time<br>Median (95% Confidence Interval)<br>Unit of measure: hours | 35.9 (24.0 to 48.0) | 48.0 (36.0 to 159.7) |

**10. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Percentage of Participants With Parasitemia |
| Measure Description | For the parasitemia assessment, blood sampling can be done by means of a finger prick except when the timing for parasitology assessments coincides with time for clinical laboratory tests, in which case, blood sample can be taken from the venous blood collected for clinical laboratory analyses. |
| Time Frame | 12, 24, 48 and 72 hours after treatment |

Analysis Population Description
mFAS. Data are reported for evaluable participants at timepoint.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|---|
| Overall Number of Participants Analyzed | | 724 | 721 |
| Core Phase: Percentage of Participants With Parasitemia<br>Number (95% Confidence Interval)<br>Unit of measure: percentage of participants | [Not specified] | | |
| 12 Hours n=719,721 | Number Analyzed | 719 participants | 721 participants |
| | | 96.9 (95.40 to 98.07) | 92.0 (89.72 to 93.84) |
| 24 Hours n=723,720 | Number Analyzed | 723 participants | 720 participants |
| | | 86.3 (83.58 to 88.73) | 62.5 (58.85 to 66.05) |
| 48 Hours n=721,721 | Number Analyzed | 721 participants | 721 participants |
| | | 15.0 (12.45 to 17.80) | 9.0 (7.03 to 11.35) |
| 72 Hours n=724,719 | Number Analyzed | 724 participants | 719 participants |
| | | 0.8 (0.30 to 1.80) | 1.7 (0.87 to 2.90) |

**11. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Clearance of Gametocytes in Participants With Gametocytemia at Baseline |
| Measure Description | Assessed by microscopy. Baseline was pre-first dose administration. |
| Time Frame | From baseline up to Day 43 |

Analysis Population Description

mFAS. Data are reported for evaluable participants at timepoint.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 726 | 722 |
| Core Phase: Clearance of Gametocytes in Participants With Gametocytemia at Baseline<br>Measure Type: Number<br>Unit of measure: percentage of participants | | |
| Day 1: Present at 6 Hours | 4.4 | 4.7 |
| Day 1: Absent at 6 Hours | 94.1 | 95.3 |
| Day 1: Missing at 6 Hours | 1.5 | 0 |
| Day 1: Present at 12 Hours | 4.5 | 4.7 |
| Day 1: Absent at 12 Hours | 94.5 | 95.2 |
| Day 1: Missing at 12 Hours | 1.0 | 0.1 |
| Day 2: Present at 24 Hours | 3.9 | 6.2 |
| Day 2: Absent at 24 Hours | 95.7 | 93.5 |
| Day 2: Missing at 24 Hours | 0.4 | 0.3 |
| Day 2: Present at 36 Hours | 2.3 | 3.6 |
| Day 2: Absent at 36 Hours | 97.2 | 96.1 |
| Day 2: Missing at 36 Hours | 0.4 | 0.3 |
| Day 3: Present | 1.1 | 3.2 |
| Day 3: Absent | 98.8 | 96.7 |
| Day 3: Missing | 0.1 | 0.1 |

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Day 4: Present | 1.0 | 1.9 |
| Day 4: Absent | 98.8 | 97.6 |
| Day 4: Missing | 0.3 | 0.4 |
| Day 8: Present | 0.1 | 1.8 |
| Day 8: Absent | 99.2 | 97.0 |
| Day 8: Missing | 0.7 | 1.2 |
| Day 22: Present | 0 | 0.3 |
| Day 22: Absent | 93.5 | 97.5 |
| Day 22: Missing | 2.2 | 2.2 |
| Day 29: Present | 0 | 0.1 |
| Day 29: Absent | 97.1 | 97.1 |
| Day 29: Missing | 2.9 | 2.8 |
| Day 43/End of Core Phase: Present | 0.1 | 0.3 |
| Day 43/End of Core Phase: Absent | 97.2 | 96.8 |
| Day 43/End of Core Phase: Missing | 2.6 | 2.9 |

**12. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Percentage of Participants With Treatment-emergent Adverse Events (TEAEs) and AEs of Grade 3 Severity or Higher |
| Measure Description | Incidence and severity of TEAEs by treatment group, including changes in vital signs, electrocardiograms (ECGs), and laboratory results qualifying and reported as AEs. Severity was graded according to the Common Terminology Criteria for Adverse Events (CTCAE): Grade 1 (Mild), Grade 2 (Moderate), Grade 3 (Severe), Grade 4 (Life-threatening), and Grade 5 (Death). |
| Time Frame | Day 43 |

Analysis Population Description

The modified safety set (mSAF) included participants who took at least one dose of study drug during the treatment period and had ≥ 10 kg body weight.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 830 | 831 |
| Core Phase: Percentage of Participants With Treatment-emergent Adverse Events (TEAEs) and AEs of Grade 3 Severity or Higher<br>Measure Type: Number<br>Unit of measure: percentage of participants | | |
| All TEAEs | 53.5 | 50.8 |
| TEAEs of Grade 3 Severity or Higher | 2.5 | 2.8 |

**13. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Core Phase: Percentage of Participants With Treatment-emergent Serious Adverse Events (SAEs), Graded by Severity |
| Measure Description | Incidence and severity of treatment-emergent SAEs by treatment group, including changes in vital signs, electrocardiograms (ECGs), and laboratory results qualifying and reported as AEs. Severity was graded according to the Common Terminology Criteria for Adverse Events (CTCAE): Grade 1 (Mild), Grade 2 (Moderate), Grade 3 (Severe), Grade 4 (Life-threatening), and Grade 5 (Death). |
| Time Frame | Day 43 |

Analysis Population Description
mSAF

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |

| | Description |
|---|---|
| Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |

Measured Values

| | KLU156 (Participants With ≥10 kg Body Weight) | Coartem (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | 830 | 831 |
| Core Phase: Percentage of Participants With Treatment-emergent Serious Adverse Events (SAEs), Graded by Severity<br>Measure Type: Number<br>Unit of measure: percentage of participants | | |
| Grade 2 | 0.2 | 0.6 |
| Grade 3 | 0.6 | 0.1 |
| Grade 4 | 0 | 0.2 |

**14. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Extension Phase: PCR-corrected ACPR |
| Measure Description | To evaluate PCR-corrected ACPR over repeated treatment with KLU156 in adults and children ≥ 10 kg of body weight suffering from uncomplicated malaria caused by P. falciparum (with or without other Plasmodium spp. co-infection). Patients were instructed to return to the study site whenever symptoms suggestive of malaria occurred. At each suspected malaria episode, eligibility for KLU156 treatment was reassessed, including confirmation of malaria diagnosis. |
| Time Frame | Up to Day 29 for each KLU156 treatment episode |

Analysis Population Description

The modified KLU156 full analysis set (mkluFAS): Patients with body weight ≥10 kg who received KLU156 at least once in the Extension phase and whose episode baseline P. falciparum asexual parasite count was ≥ 200 and ≤ 200,000 parasites/µL. For patients treated with KLU156 in the Core phase, Core phase data up to Day 33 were also included.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | | 342 |
| Extension Phase: PCR-corrected ACPR<br>Number (95% Confidence Interval)<br>Unit of measure: percentage of participants | [Not specified] | |
| 1st KLU156 Treatment n=342 | Number Analyzed | 342 participants |
| | | 98.0 (95.8 to 99.2) |
| 2nd KLU156 Treatment n=214 | Number Analyzed | 214 participants |
| | | 97.2 (94.0 to 99.0) |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) n=59 | Number Analyzed | 59 participants |
| | | 100.0 (93.9 to 100.0) |

**15. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Extension Phase: Uncorrected ACPR |
| Measure Description | To evaluate uncorrected ACPR over repeated treatment with KLU156 in adults and children ≥ 10 kg of body weight suffering from uncomplicated malaria caused by P. falciparum (with or without other Plasmodium spp. co-infection). |
| Time Frame | Up to Day 29 for each KLU156 treatment episode |

Analysis Population Description
mkluFAS

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | | 362 |
| Extension Phase: Uncorrected ACPR<br>Number (95% Confidence Interval)<br>Unit of measure: percentage of participants | [Not specified] | |
| 1st KLU156 Treatment n=362 | Number Analyzed | 362 participants |
| | | 86.5 (82.5 to 89.8) |
| 2nd KLU156 Treatment n=222 | Number Analyzed | 222 participants |
| | | 87.4 (82.3 to 91.5) |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) n=59 | Number Analyzed | 59 participants |
| | | 88.1 (77.1 to 95.1) |

**16. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Extension Phase: Percentage of Participants With KLU156-related AEs by Malaria Episode |
| Measure Description | To assess the safety and tolerability over repeated treatment with KLU156 in adults and children ≥ 10 kg of body weight suffering from uncomplicated malaria caused by P. falciparum (with or without other Plasmodium spp. co-infection). |
| Time Frame | Up to approximately 18 months |

Analysis Population Description

The modified KLU156 safety analysis set (mkluSAF) included all patients in the modified KLU156 analysis set with body weight ≥ 10 kg in the extension phase who received at least one KLU156 treatment in the extension phase.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | | 393 |
| Extension Phase: Percentage of Participants With KLU156-related AEs by Malaria Episode<br>Measure Type: Number<br>Unit of measure: percentage of participants | [Not specified] | |
| 1st KLU156 Treatment n=393 | Number Analyzed | 393 participants |
| | | 12.2 |
| 2nd KLU156 Treatment n=230 | Number Analyzed | 230 participants |
| | | 9.1 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) n=62 | Number Analyzed | 62 participants |
| | | 11.3 |

**17. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Extension Phase: Percentage of Participants With SAEs by Severity and Malaria Episode |
| Measure Description | To assess the safety and tolerability over repeated treatment with KLU156 in adults and children ≥ 10 kg of body weight suffering from uncomplicated malaria caused by P. falciparum (with or without other Plasmodium spp. co-infection). |
| Time Frame | Up to approximately 18 months |

Analysis Population Description
mkluSAF

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | | 393 |
| Extension Phase: Percentage of Participants With SAEs by Severity and Malaria Episode<br>Measure Type: Number<br>Unit of measure: percentage of participants | [Not specified] | |
| 1st KLU156 Treatment n=393 | Number Analyzed | 393 participants |
| | | 0 |
| 2nd KLU156 Treatment n=230 | Number Analyzed | 230 participants |
| | | 0 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) n=62 | Number Analyzed | 62 participants |
| | | 0 |

**18. Secondary Outcome Measure:**

| | |
|---|---|
| Measure Title | Extension Phase: Gametocyte Carriage Over Time |
| Measure Description | To assess gametocyte carriage over time by malaria episode in the extension phase |
| Time Frame | Up to Day 29 for each KLU156 treatment episode |

Analysis Population Description

mkluFAS. Results are reported for participants with data at timepoint.

Reporting Groups

| | Description |
|---|---|
| KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |

Measured Values

| | | KLU156 (Participants With ≥10 kg Body Weight) |
|---|---|---|
| Overall Number of Participants Analyzed | | 362 |
| Extension Phase: Gametocyte Carriage Over Time<br>Measure Type: Number<br>Unit of measure: percentage of participants | [Not specified] | |
| 1st KLU156 Treatment, Present at Day 3 n=362 | Number Analyzed | 362 participants |
| | | 1.1 |
| 1st KLU156 Treatment, Absent at Day 3 n=362 | Number Analyzed | 362 participants |
| | | 98.9 |
| 2nd KLU156 Treatment Present at Day 3 n=222 | Number Analyzed | 222 participants |
| | | 0.5 |
| 2nd KLU156 Treatment Absent at Day 3 n=222 | Number Analyzed | 222 participants |
| | | 99.1 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Present at Day 3 n=59 | Number Analyzed | 59 participants |
| | | 0 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Absent at Day 3 n=59 | Number Analyzed | 59 participants |
| | | 100 |
| 1st KLU156 Treatment, Present at Day 4 n=362 | Number Analyzed | 362 participants |
| | | 0.8 |
| 1st KLU156 Treatment, Absent at Day 4 n=362 | Number Analyzed | 362 participants |
| | | 98.9 |
| 2nd KLU156 Treatment Present at Day 4 n=222 | Number Analyzed | 222 participants |
| | | 0 |

| | | KLU156 (Participants With ≥10 kg Body Weight) |
|---|---|---|
| 2nd KLU156 Treatment Absent at Day 4 n=222 | Number Analyzed | 222 participants |
| | | 100 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Present at Day 4 n=59 | Number Analyzed | 59 participants |
| | | 0 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Absent at Day 4 n=59 | Number Analyzed | 59 participants |
| | | 100 |
| 1st KLU156 Treatment, Present at Day 8 n=362 | Number Analyzed | 362 participants |
| | | 0 |
| 1st KLU156 Treatment, Absent at Day 8 n=362 | Number Analyzed | 362 participants |
| | | 99.4 |
| 2nd KLU156 Treatment Present at Day 8 n=222 | Number Analyzed | 222 participants |
| | | 0 |
| 2nd KLU156 Treatment Absent at Day 8 n=222 | Number Analyzed | 222 participants |
| | | 100 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Present at Day 8 n=59 | Number Analyzed | 59 participants |
| | | 0 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Absent at Day 8 n=59 | Number Analyzed | 59 participants |
| | | 100 |
| 1st KLU156 Treatment, Present at Day 29 n=362 | Number Analyzed | 362 participants |
| | | 0 |
| 1st KLU156 Treatment, Absent at Day 29 n=362 | Number Analyzed | 362 participants |

| | | KLU156 (Participants With ≥10 kg Body Weight) |
|---|---|---|
| | | 98.9 |
| 2nd KLU156 Treatment Present at Day 29 n=222 | Number Analyzed | 222 participants |
| | | 0 |
| 2nd KLU156 Treatment Absent at Day 29 n=222 | Number Analyzed | 222 participants |
| | | 99.1 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Present at Day 29 n=59 | Number Analyzed | 59 participants |
| | | 0 |
| 3rd+ KLU156 Treatment Onward (includes 3rd, 4th, 5th, and 6th KLU156 groups) Absent at Day 29 n=59 | Number Analyzed | 59 participants |
| | | 100 |

## Reported Adverse Events

| | |
|---|---|
| Time Frame | Adverse events were reported from the first dose of study treatment until the end of study treatment plus a follow-up period, up to a maximum of approximately 20 months. |
| Adverse Event Reporting Description | The safety set included all participants who took at least one dose of study drug during the treatment period of the study. Safety data are reported for all treated patients, regardless of body weight. |

Reporting Groups

| | Description |
|---|---|
| Core Phase: KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Core Phase: Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |
| Core Phase: Total (Participants With ≥10 kg Body Weight) | Core Phase: Total (Participants with ≥10 kg Body Weight) |

| | Description |
|---|---|
| Extension Phase: KLU156 (Participants With ≥10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Extension Phase: Coartem (Participants With ≥10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |
| Extension Phase: Total (Participants With ≥10 kg Body Weight) | Extension Phase: Total (Participants with ≥10 kg Body Weight) |
| Core Phase: KLU156 (Participants With <10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Core Phase: Coartem (Participants With <10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |
| Core Phase: Total (Participants With <10 kg Body Weight) | Core Phase: Total (Participants with <10 kg Body Weight) |
| Extension Phase: KLU156 (Participants With <10 kg Body Weight) | KLU156 once daily (QD) for 3 days under fed conditions (light meal). |
| Extension Phase: Coartem (Participants With <10 kg Body Weight) | Coartem twice a day (BID) for 3 days under fed conditions. |
| Extension Phase: Total (Participants With <10 kg Body Weight) | Extension Phase: Total (Participants with <10 kg Body Weight) |

**All-Cause Mortality**

| | Core Phase: KLU156 (Participants With ≥10 kg Body Weight) | Core Phase: Coartem (Participants With ≥10 kg Body Weight) | Core Phase: Total (Participants With ≥10 kg Body Weight) | Extension Phase: KLU156 (Participants With ≥10 kg Body Weight) | Extension Phase: Coartem (Participants With ≥10 kg Body Weight) | Extension Phase: Total (Participants With ≥10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total All-Cause Mortality | 0/830 (0%) | 1/831 (0.12%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |

| | Core Phase: KLU156 (Participants With <10 kg Body Weight) | Core Phase: Coartem (Participants With <10 kg Body Weight) | Core Phase: Total (Participants With <10 kg Body Weight) | Extension Phase: KLU156 (Participants With <10 kg Body Weight) | Extension Phase: Coartem (Participants With <10 kg Body Weight) | Extension Phase: Total (Participants With <10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total All-Cause Mortality | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |

**Serious Adverse Events**

| | Core Phase: KLU156 (Participants With ≥10 kg Body Weight) | Core Phase: Coartem (Participants With ≥10 kg Body Weight) | Core Phase: Total (Participants With ≥10 kg Body Weight) | Extension Phase: KLU156 (Participants With ≥10 kg Body Weight) | Extension Phase: Coartem (Participants With ≥10 kg Body Weight) | Extension Phase: Total (Participants With ≥10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total | 7/830 (0.84%) | 8/831 (0.96%) | 15/1661 (0.9%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Blood and lymphatic system disorders | | | | | | |
| Anaemia [A] † | 2/830 (0.24%) | 1/831 (0.12%) | 3/1661 (0.18%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Cardiac disorders | | | | | | |
| Supraventricular tachycardia [A] † | 1/830 (0.12%) | 0/831 (0%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Gastrointestinal disorders | | | | | | |
| Intussusception [A] † | 1/830 (0.12%) | 0/831 (0%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Vomiting [A] † | 1/830 (0.12%) | 0/831 (0%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Infections and infestations | | | | | | |
| Cellulitis [A] † | 1/830 (0.12%) | 0/831 (0%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Furuncle [A] † | 0/830 (0%) | 0/831 (0%) | 0/1661 (0%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Hepatitis viral [A] † | 0/830 (0%) | 1/831 (0.12%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Malaria [A] † | 0/830 (0%) | 1/831 (0.12%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Otitis media acute [A] † | 0/830 (0%) | 1/831 (0.12%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |

| | Core Phase: KLU156 (Participants With ≥10 kg Body Weight) | Core Phase: Coartem (Participants With ≥10 kg Body Weight) | Core Phase: Total (Participants With ≥10 kg Body Weight) | Extension Phase: KLU156 (Participants With ≥10 kg Body Weight) | Extension Phase: Coartem (Participants With ≥10 kg Body Weight) | Extension Phase: Total (Participants With ≥10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Pneumonia [A] † | 1/830 (0.12%) | 1/831 (0.12%) | 2/1661 (0.12%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Injury, poisoning and procedural complications | | | | | | |
| Lower limb fracture [A] † | 0/830 (0%) | 1/831 (0.12%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Snake bite [A] † | 0/830 (0%) | 1/831 (0.12%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Investigations | | | | | | |
| Blood creatinine increased [A] † | 0/830 (0%) | 1/831 (0.12%) | 1/1661 (0.06%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Hepatic enzyme increased [A] † | 0/830 (0%) | 0/831 (0%) | 0/1661 (0%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Liver function test increased [A] † | 0/830 (0%) | 0/831 (0%) | 0/1661 (0%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Metabolism and nutrition disorders | | | | | | |
| Dehydration [A] † | 0/830 (0%) | 0/831 (0%) | 0/1661 (0%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (28.1)

| | Core Phase: KLU156 (Participants With <10 kg Body Weight) | Core Phase: Coartem (Participants With <10 kg Body Weight) | Core Phase: Total (Participants With <10 kg Body Weight) | Extension Phase: KLU156 (Participants With <10 kg Body Weight) | Extension Phase: Coartem (Participants With <10 kg Body Weight) | Extension Phase: Total (Participants With <10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total | 2/24 (8.33%) | 2/27 (7.41%) | 4/51 (7.84%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Blood and lymphatic system disorders | | | | | | |
| Anaemia [A] † | 1/24 (4.17%) | 0/27 (0%) | 1/51 (1.96%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Cardiac disorders | | | | | | |

| | Core Phase: KLU156 (Participants With <10 kg Body Weight) | Core Phase: Coartem (Participants With <10 kg Body Weight) | Core Phase: Total (Participants With <10 kg Body Weight) | Extension Phase: KLU156 (Participants With <10 kg Body Weight) | Extension Phase: Coartem (Participants With <10 kg Body Weight) | Extension Phase: Total (Participants With <10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Supraventricular tachycardia [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Gastrointestinal disorders | | | | | | |
| Intussusception [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Vomiting [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Infections and infestations | | | | | | |
| Cellulitis [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Furuncle [A] † | 1/24 (4.17%) | 0/27 (0%) | 1/51 (1.96%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Hepatitis viral [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Malaria [A] † | 0/24 (0%) | 1/27 (3.7%) | 1/51 (1.96%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Otitis media acute [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Pneumonia [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Injury, poisoning and procedural complications | | | | | | |
| Lower limb fracture [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Snake bite [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Investigations | | | | | | |
| Blood creatinine increased [A] † | 0/24 (0%) | 0/27 (0%) | 0/51 (0%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Hepatic enzyme increased [A] † | 1/24 (4.17%) | 0/27 (0%) | 1/51 (1.96%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Liver function test increased [A] † | 0/24 (0%) | 1/27 (3.7%) | 1/51 (1.96%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Metabolism and nutrition disorders | | | | | | |
| Dehydration [A] † | 1/24 (4.17%) | 0/27 (0%) | 1/51 (1.96%) | 0/2 (0%) | 0/0 | 0/2 (0%) |

† Indicates events were collected by systematic assessment.

A Term from vocabulary, MedDRA (28.1)

**Other Adverse Events**

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

| | Core Phase: KLU156 (Participants With ≥10 kg Body Weight) | Core Phase: Coartem (Participants With ≥10 kg Body Weight) | Core Phase: Total (Participants With ≥10 kg Body Weight) | Extension Phase: KLU156 (Participants With ≥10 kg Body Weight) | Extension Phase: Coartem (Participants With ≥10 kg Body Weight) | Extension Phase: Total (Participants With ≥10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total | 361/830 (43.49%) | 339/831 (40.79%) | 700/1661 (42.14%) | 59/190 (31.05%) | 64/203 (31.53%) | 123/393 (31.3%) |
| Blood and lymphatic system disorders | | | | | | |
| Anaemia [A] † | 68/830 (8.19%) | 69/831 (8.3%) | 137/1661 (8.25%) | 9/190 (4.74%) | 10/203 (4.93%) | 19/393 (4.83%) |
| Gastrointestinal disorders | | | | | | |
| Diarrhoea [A] † | 4/830 (0.48%) | 3/831 (0.36%) | 7/1661 (0.42%) | 2/190 (1.05%) | 3/203 (1.48%) | 5/393 (1.27%) |
| Enteritis [A] † | 4/830 (0.48%) | 3/831 (0.36%) | 7/1661 (0.42%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Vomiting [A] † | 155/830 (18.67%) | 37/831 (4.45%) | 192/1661 (11.56%) | 19/190 (10%) | 16/203 (7.88%) | 35/393 (8.91%) |
| General disorders | | | | | | |
| Pyrexia [A] † | 74/830 (8.92%) | 104/831 (12.52%) | 178/1661 (10.72%) | 10/190 (5.26%) | 10/203 (4.93%) | 20/393 (5.09%) |
| Infections and infestations | | | | | | |
| Bronchitis [A] † | 9/830 (1.08%) | 15/831 (1.81%) | 24/1661 (1.44%) | 5/190 (2.63%) | 3/203 (1.48%) | 8/393 (2.04%) |
| Gastroenteritis [A] † | 4/830 (0.48%) | 4/831 (0.48%) | 8/1661 (0.48%) | 0/190 (0%) | 3/203 (1.48%) | 3/393 (0.76%) |
| Malaria [A] † | 135/830 (16.27%) | 193/831 (23.23%) | 328/1661 (19.75%) | 23/190 (12.11%) | 21/203 (10.34%) | 44/393 (11.2%) |
| Rhinitis [A] † | 21/830 (2.53%) | 16/831 (1.93%) | 37/1661 (2.23%) | 4/190 (2.11%) | 3/203 (1.48%) | 7/393 (1.78%) |
| Investigations | | | | | | |

| | Core Phase: KLU156 (Participants With ≥10 kg Body Weight) | Core Phase: Coartem (Participants With ≥10 kg Body Weight) | Core Phase: Total (Participants With ≥10 kg Body Weight) | Extension Phase: KLU156 (Participants With ≥10 kg Body Weight) | Extension Phase: Coartem (Participants With ≥10 kg Body Weight) | Extension Phase: Total (Participants With ≥10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Electrocardiogram QT prolonged [A] † | 22/830 (2.65%) | 7/831 (0.84%) | 29/1661 (1.75%) | 10/190 (5.26%) | 6/203 (2.96%) | 16/393 (4.07%) |
| Respiratory, thoracic and mediastinal disorders | | | | | | |
| Cough [A] † | 17/830 (2.05%) | 13/831 (1.56%) | 30/1661 (1.81%) | 6/190 (3.16%) | 4/203 (1.97%) | 10/393 (2.54%) |
| Rhinitis allergic [A] † | 2/830 (0.24%) | 3/831 (0.36%) | 5/1661 (0.3%) | 0/190 (0%) | 0/203 (0%) | 0/393 (0%) |
| Rhinorrhoea [A] † | 2/830 (0.24%) | 3/831 (0.36%) | 5/1661 (0.3%) | 1/190 (0.53%) | 0/203 (0%) | 1/393 (0.25%) |

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (28.1)

| | Core Phase: KLU156 (Participants With <10 kg Body Weight) | Core Phase: Coartem (Participants With <10 kg Body Weight) | Core Phase: Total (Participants With <10 kg Body Weight) | Extension Phase: KLU156 (Participants With <10 kg Body Weight) | Extension Phase: Coartem (Participants With <10 kg Body Weight) | Extension Phase: Total (Participants With <10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Total | 20/24 (83.33%) | 16/27 (59.26%) | 36/51 (70.59%) | 2/2 (100%) | 0/0 | 2/2 (100%) |
| Blood and lymphatic system disorders | | | | | | |
| Anaemia [A] † | 4/24 (16.67%) | 3/27 (11.11%) | 7/51 (13.73%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Gastrointestinal disorders | | | | | | |
| Diarrhoea [A] † | 2/24 (8.33%) | 0/27 (0%) | 2/51 (3.92%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Enteritis [A] † | 1/24 (4.17%) | 2/27 (7.41%) | 3/51 (5.88%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Vomiting [A] † | 15/24 (62.5%) | 2/27 (7.41%) | 17/51 (33.33%) | 2/2 (100%) | 0/0 | 2/2 (100%) |
| General disorders | | | | | | |
| Pyrexia [A] † | 6/24 (25%) | 4/27 (14.81%) | 10/51 (19.61%) | 0/2 (0%) | 0/0 | 0/2 (0%) |

| | Core Phase: KLU156 (Participants With <10 kg Body Weight) | Core Phase: Coartem (Participants With <10 kg Body Weight) | Core Phase: Total (Participants With <10 kg Body Weight) | Extension Phase: KLU156 (Participants With <10 kg Body Weight) | Extension Phase: Coartem (Participants With <10 kg Body Weight) | Extension Phase: Total (Participants With <10 kg Body Weight) |
|---|---|---|---|---|---|---|
| | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) | Affected/ At Risk (%) |
| Infections and infestations | | | | | | |
| Bronchitis [A] † | 2/24 (8.33%) | 5/27 (18.52%) | 7/51 (13.73%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Gastroenteritis [A] † | 1/24 (4.17%) | 0/27 (0%) | 1/51 (1.96%) | 1/2 (50%) | 0/0 | 1/2 (50%) |
| Malaria [A] † | 1/24 (4.17%) | 4/27 (14.81%) | 5/51 (9.8%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Rhinitis [A] † | 2/24 (8.33%) | 3/27 (11.11%) | 5/51 (9.8%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Investigations | | | | | | |
| Electrocardiogram QT prolonged [A] † | 0/24 (0%) | 1/27 (3.7%) | 1/51 (1.96%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Respiratory, thoracic and mediastinal disorders | | | | | | |
| Cough [A] † | 3/24 (12.5%) | 0/27 (0%) | 3/51 (5.88%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Rhinitis allergic [A] † | 2/24 (8.33%) | 1/27 (3.7%) | 3/51 (5.88%) | 0/2 (0%) | 0/0 | 0/2 (0%) |
| Rhinorrhoea [A] † | 1/24 (4.17%) | 2/27 (7.41%) | 3/51 (5.88%) | 0/2 (0%) | 0/0 | 0/2 (0%) |

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (28.1)

## Limitations and Caveats

[Not specified]

## More Information

**Certain Agreements:**

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

**Results Point of Contact:**

Name/Official Title: Study Director
Organization: Novartis Pharmaceuticals
Phone: + 1 862 778 8300
Email: Novartis.email@Novartis.com