# Clinical trial results:
# A Phase 2/3, Open-Label Study of the Pharmacokinetics, Safety, and Antiviral Activity of the Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (E/C/F/TAF) Single Tablet Regimen (STR) in HIV-1 Infected Antiretroviral Treatment-Naive Adolescents and Virologically Suppressed Children

## Summary

| | |
|---|---|
| EudraCT number | 2013-002780-26 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 18 June 2025 |

### Results information

| | |
|---|---|
| Result version number | v2 (current) |
| This version publication date | 02 January 2026 |
| First version publication date | 13 June 2021 |
| Version creation reason | • New data added to full data set<br>New data set added for the final results posting. |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | GS-US-292-0106 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01854775 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Gilead Sciences |
| Sponsor organisation address | 333 Lakeside Drive, Foster City, CA, United States, 94404 |
| Public contact | Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com |
| Scientific contact | Gilead Clinical Study Information Center, Gilead Sciences, GileadClinicalTrials@gilead.com |

Notes:

### Paediatric regulatory details

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMEA-001460-PIP01-13 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 18 June 2025 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 18 June 2025 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objectives of Cohort 1 were to evaluate the steady state pharmacokinetics (PK) for elvitegravir (EVG) and TAF and confirm the dose of E/C/F/TAF STR (Part A) and to evaluate the safety and tolerability of E/C/F/TAF single-tablet regimen (STR) through Week 24 (Part B) in HIV-1 infected, antiretroviral (ARV) treatment-naive adolescents. The primary objectives of Cohort 2 were to evaluate the PK of EVG and TAF in virologically suppressed HIV-1 infected children 6 to < 12 years of age weighing ≥ 25 kg administered E/C/F/TAF STR (Part A) and to evaluate the safety and tolerability of E/C/F/TAF STR through Week 24 in virologically suppressed HIV-1 infected children 6 to < 12 years of age weighing ≥ 25 kg (Part B). The primary objectives of Cohort 3 were to evaluate the PK of EVG and TAF and confirm the dose of STR, and to evaluate the safety and tolerability of E/C/F/TAF low dose STR in virologically suppressed HIV-1 infected children ≥ 2 years of age and weighing ≥ 14 < 25 kg.

Protection of trial subjects:

The protocol and consent/assent forms were submitted by each investigator to a duly constituted Independent Ethics Committee (IEC) or Institutional Review Board (IRB) for review and approval before study initiation. All revisions to the consent/assent forms (if applicable) after initial IEC/IRB approval were submitted by the investigator to the IEC/IRB for review and approval before implementation in accordance with regulatory requirements.

This study was conducted in accordance with recognized international scientific and ethical standards, including but not limited to the International Conference on Harmonization guideline for Good Clinical Practice (ICH GCP) and the original principles embodied in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 06 May 2013 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Thailand: 20 |
| Country: Number of subjects enrolled | South Africa: 16 |
| Country: Number of subjects enrolled | Uganda: 65 |
| Country: Number of subjects enrolled | United States: 26 |
| Country: Number of subjects enrolled | Zimbabwe: 2 |
| Worldwide total number of subjects | 129 |
| EEA total number of subjects | 0 |

Notes:

| Subjects enrolled per age group | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 79 |
| Adolescents (12-17 years) | 50 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Participants were enrolled at study sites in South Africa, Thailand, Uganda, United States of America, and Zimbabwe.

### Pre-assignment

Screening details:

155 participants were screened.

### Period 1

| | |
|---|---|
| Period 1 title | Treatment Phase (48 Weeks) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg |

Arm description:

Treatment naive adolescents (12 to < 18 years of age) with human immunodeficiency virus (HIV) received elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) (150/150/200/10 mg) fixed-dose combination (FDC) tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | E/C/F/TAF |
| Investigational medicinal product code | |
| Other name | Genvoya® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablets administered once daily.

| | |
|---|---|
| **Arm title** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg |

Arm description:

Children (6 to < 12 years of age weighing ≥ 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (150/150/200/10 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | E/C/F/TAF |
| Investigational medicinal product code | |
| Other name | Genvoya® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablets administered once daily.

| | |
|---|---|
| **Arm title** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |

Arm description:

Children (≥ 2 years of age weighing ≥ 14 to < 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (90/90/120/6 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who attained a weight of ≥ 25 kg during the course of the study were switched to adult E/C/F/TAF (150/150/200/10 mg) tablets administered orally, once daily with food. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | E/C/F/TAF (Low Dose) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablets administered once daily.

| **Number of subjects in period 1** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |
|---|---|---|---|
| Started | 50 | 52 | 27 |
| Completed | 48 | 51 | 27 |
| Not completed | 2 | 1 | 0 |
| Lost to follow-up | 1 | - | - |
| Withdrew consent | 1 | 1 | - |

## Period 2

| | |
|---|---|
| Period 2 title | Extension Phase |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

## Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Extension Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg |

Arm description:

Treatment naive adolescents (12 to < 18 years of age) with human immunodeficiency virus (HIV) received elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) (150/150/200/10 mg) fixed-dose combination (FDC) tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Arm type | Experimental |

| | |
|---|---|
| Investigational medicinal product name | E/C/F/TAF |
| Investigational medicinal product code | |
| Other name | Genvoya® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablets administered once daily.

| | |
|---|---|
| **Arm title** | Extension Ph: Age 6 to < 12 Years and Weight ≥ 25 kg |

Arm description:

Children (6 to < 12 years of age weighing ≥ 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (150/150/200/10 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | E/C/F/TAF |
| Investigational medicinal product code | |
| Other name | Genvoya® |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablets administered once daily.

| | |
|---|---|
| **Arm title** | Extension Ph : Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |

Arm description:

Children (≥ 2 years of age weighing ≥ 14 to < 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (90/90/120/6 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who attained a weight of ≥ 25 kg during the course of the study were switched to adult E/C/F/TAF (150/150/200/10 mg) tablets administered orally, once daily with food. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | E/C/F/TAF (Low Dose) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Tablets administered once daily.

| **Number of subjects in period 2[1]** | Extension Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | Extension Ph: Age 6 to < 12 Years and Weight ≥ 25 kg | Extension Ph : Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |
|---|---|---|---|
| Started | 48 | 50 | 27 |
| Completed | 44 | 49 | 27 |
| Not completed | 4 | 1 | 0 |
| Non- Compliance with Study Drug | 1 | - | - |
| Investigator's Discretion | 1 | - | - |

| | | | |
|---|---|---|---|
| Pregnancy | 1 | - | - |
| Lost to follow-up | 1 | - | - |
| Withdrew consent | - | 1 | - |

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: 1 participant in arm 'Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg' completed the Treatment Phase, but did not enter in the Extension Phase.

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg |

Reporting group description:

Treatment naive adolescents (12 to < 18 years of age) with human immunodeficiency virus (HIV) received elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) (150/150/200/10 mg) fixed-dose combination (FDC) tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group title | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg |
|---|---|

Reporting group description:

Children (6 to < 12 years of age weighing ≥ 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (150/150/200/10 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group title | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |
|---|---|

Reporting group description:

Children (≥ 2 years of age weighing ≥ 14 to < 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (90/90/120/6 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who attained a weight of ≥ 25 kg during the course of the study were switched to adult E/C/F/TAF (150/150/200/10 mg) tablets administered orally, once daily with food. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |
|---|---|---|---|
| Number of subjects | 50 | 52 | 27 |
| Age categorical<br>Units: Subjects | | | |
| 2 to <6 Years | 0 | 0 | 11 |
| 6 to <12 Years | 0 | 52 | 16 |
| 12 to <18 Years | 50 | 0 | 0 |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 15 | 10 | 6 |
| standard deviation | ± 1.9 | ± 1.2 | ± 1.9 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 28 | 30 | 17 |
| Male | 22 | 22 | 10 |
| Ethnicity<br>Units: Subjects | | | |
| Not Hispanic or Latino | 50 | 52 | 27 |
| Race | | | |

| | | | |
|---|---|---|---|
| Units: Subjects | | | |
| Asian | 6 | 13 | 3 |
| Black or African American | 44 | 37 | 24 |
| White | 0 | 2 | 0 |

| **Reporting group values** | Total | | |
|---|---|---|---|
| Number of subjects | 129 | | |
| Age categorical<br>Units: Subjects | | | |
| 2 to <6 Years | 11 | | |
| 6 to <12 Years | 68 | | |
| 12 to <18 Years | 50 | | |
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | -<br>- | | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 75 | | |
| Male | 54 | | |
| Ethnicity<br>Units: Subjects | | | |
| Not Hispanic or Latino | 129 | | |
| Race<br>Units: Subjects | | | |
| Asian | 22 | | |
| Black or African American | 105 | | |
| White | 2 | | |

## End points

### End points reporting groups

| Reporting group title | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg |
|---|---|

Reporting group description:

Treatment naive adolescents (12 to < 18 years of age) with human immunodeficiency virus (HIV) received elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) (150/150/200/10 mg) fixed-dose combination (FDC) tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group title | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg |
|---|---|

Reporting group description:

Children (6 to < 12 years of age weighing ≥ 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (150/150/200/10 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group title | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |
|---|---|

Reporting group description:

Children (≥ 2 years of age weighing ≥ 14 to < 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (90/90/120/6 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who attained a weight of ≥ 25 kg during the course of the study were switched to adult E/C/F/TAF (150/150/200/10 mg) tablets administered orally, once daily with food. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group title | Extension Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg |
|---|---|

Reporting group description:

Treatment naive adolescents (12 to < 18 years of age) with human immunodeficiency virus (HIV) received elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) (150/150/200/10 mg) fixed-dose combination (FDC) tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group title | Extension Ph: Age 6 to < 12 Years and Weight ≥ 25 kg |
|---|---|

Reporting group description:

Children (6 to < 12 years of age weighing ≥ 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (150/150/200/10 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| Reporting group title | Extension Ph : Age ≥ 2 Years and Weight ≥ 14 to < 25 kg |
|---|---|

Reporting group description:

Children (≥ 2 years of age weighing ≥ 14 to < 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (90/90/120/6 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who attained a weight of ≥ 25 kg during the course of the study were switched to adult E/C/F/TAF (150/150/200/10 mg) tablets administered orally, once daily with food. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

## Primary: Pharmacokinetic (PK) Parameter: AUCtau of Elvitegravir (EVG) (Cohort 1)

| End point title | Pharmacokinetic (PK) Parameter: AUCtau of Elvitegravir (EVG) (Cohort 1)[1][2] |
|---|---|

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration versus time curve over the dosing interval). The PK Substudy Analysis Set included all enrolled and treated participants from Part A who had any nonmissing key PK parameters (AUCtau, AUClast, Cmax) from Week 4 intensive PK data for the respective analyte.

| End point type | Primary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 5 minutes, 0.25, 0.5, 1, 1.5, 2, 4, 5, 8 and 24 hours post-dose at Week 4

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | 23840.1 (± 6076.15) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: PK Parameter: AUCtau of EVG (Cohort 2)

| End point title | PK Parameter: AUCtau of EVG (Cohort 2)[3][4] |
|---|---|

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration versus time curve over the dosing interval). Participants in the PK Substudy Analysis Set with available data were analyzed.

| End point type | Primary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 8, and 24 hours post-dose at Week 4

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The end point is reporting statistics for Cohort 2 only.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| End point values | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 22 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | 33813.9 (± 19536.30) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: PK Parameter: AUCtau of EVG (Cohort 3)

| End point title | PK Parameter: AUCtau of EVG (Cohort 3)[5][6] |
|---|---|

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration versus time curve over the dosing interval). The Intensive PK Analysis Set included all enrolled and treated participants who had any nonmissing key PK parameters (AUCtau, AUClast, Cmax) from Week 2 intensive PK data for the respective analyte.

| End point type | Primary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, and 8 hours post-dose at Week 2

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| End point values | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | 33245.6 (± 15499.22) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: PK Parameter: AUClast of Tenofovir Alafenamide (TAF) (Cohort 1)

| End point title | PK Parameter: AUClast of Tenofovir Alafenamide (TAF) (Cohort 1)[7][8] |
|---|---|

End point description:

AUClast is defined as the concentration of drug from time zero to the last observable concentration, area under the concentration time curve to last observation (AUClast). Participants in the PK Substudy Analysis Set were analyzed.

| End point type | Primary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 5 minutes, 0.25, 0.5, 1, 1.5, 2, 4, 5, 8 and 24 hours post-dose at Week 4

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | 188.9 (± 105.45) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: PK Parameter: AUClast of TAF (Cohort 2)

| End point title | PK Parameter: AUClast of TAF (Cohort 2)[9][10] |
|---|---|

End point description:

AUClast is defined as the concentration of drug from time zero to the last observable concentration. Participants in the PK Substudy Analysis set were analyzed.

| End point type | Primary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 8, and 24 hours post-dose at Week 4

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| End point values | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 23 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | 332.9 (± 149.12) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: PK Parameter: AUCtau of TAF (Cohort 3)

| End point title | PK Parameter: AUCtau of TAF (Cohort 3)[11][12] |
|---|---|

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration versus time curve over the dosing interval). Participants in the Intensive PK Analysis Set (all enrolled and treated participants who had any nonmissing key PK parameters [AUCtau, AUClast, Cmax] from Week 2 intensive PK data for the respective analyte) with available data were analyzed.

| End point type | Primary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, and 8 hours post-dose at Week 2

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The end point is reporting statistics for Cohort 2 only.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| End point values | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | 366.4 (± 144.91) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 1: Percentage of Participants With All Treatment-Emergent Adverse Events (AEs) and Treatment-Emergent Serious Adverse Events (SAEs)

| End point title | Cohort 1: Percentage of Participants With All Treatment-Emergent Adverse Events (AEs) and Treatment-Emergent Serious Adverse Events (SAEs)[13][14] |
|---|---|

End point description:

Treatment-emergent adverse events (TEAEs) were defined as any AEs that begin or worsen on or after the start of study drug through 30 days after the last dose of study drug. The severity was graded based on the Gilead Sciences Grading Scale for Severity of Adverse Events. An AE that met one or more of the following outcomes was classified as serious:
• Fatal
• Life-threatening
• Disabling/incapacitating
• Results in hospitalization or prolongs a hospital stay
• A congenital abnormality
• Other important medical events may also be considered serious AEs if they may require medical or surgical intervention to prevent one of the outcomes listed above. Participants in the Safety Analysis Set (all participants who received at least 1 dose of study drug) with available data were analyzed.

| End point type | Primary |
|---|---|

End point timeframe:

From first dose date up to Week 24

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 48 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Any TEAEs | 81.3 | | | |
| SAEs | 8.3 | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 2: Percentage of Participants With All Treatment-Emergent AEs and Treatment-Emergent SAEs

| End point title | Cohort 2: Percentage of Participants With All Treatment-Emergent AEs and Treatment-Emergent SAEs[15][16] |
|---|---|

End point description:

TEAEs were defined as any AEs that begin or worsen on or after the start of study drug through 30 days after the last dose of study drug. The severity was graded based on the Gilead Sciences Grading Scale for Severity of Adverse Events. An AE that met one or more of the following outcomes was classified as serious:
• Fatal
• Life-threatening
• Disabling/incapacitating
• Results in hospitalization or prolongs a hospital stay

• A congenital abnormality
• Other important medical events may also be considered serious AEs if they may require medical or surgical intervention to prevent one of the outcomes listed above. Participants in the Safety Analysis Set with available data were analyzed.

| End point type | Primary |
|---|---|

End point timeframe:

From first dose date up to Week 24

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 23 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Any TEAEs | 73.9 | | | |
| SAEs | 0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Cohort 3: Percentage of Participants With All Treatment-Emergent AEs and Treatment-Emergent SAEs

| End point title | Cohort 3: Percentage of Participants With All Treatment-Emergent AEs and Treatment-Emergent SAEs[17][18] |
|---|---|

End point description:

TEAEs were defined as any AEs that begin or worsen on or after the start of study drug through 30 days after the last dose of study drug. The severity was graded based on the Gilead Sciences Grading Scale for Severity of Adverse Events. An AE that met one or more of the following outcomes was classified as serious:
• Fatal
• Life-threatening
• Disabling/incapacitating
• Results in hospitalization or prolongs a hospital stay
• A congenital abnormality
• Other important medical events may also be considered serious AEs if they may require medical or surgical intervention to prevent one of the outcomes listed above. Participants in the Safety Analysis Set were analyzed.

| End point type | Primary |
|---|---|

End point timeframe:

From first dose date up to Week 24

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical comparison was planned or performed.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Any TEAEs | 70.4 | | | |
| SAEs | 3.7 | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Ctau of EVG, FTC, TFV, and COBI (Cohort 1)

| End point title | PK Parameter: Ctau of EVG, FTC, TFV, and COBI (Cohort 1)[19] |
|---|---|

End point description:

Ctau is defined as the observed drug concentration at the end of the dosing interval. Participants in the PK Substudy Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 5 minutes, 0.25, 0.5, 1, 1.5, 2, 4, 5, 8 and 24 hours post-dose at Week 4

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n = 24) | 300.8 (± 243.69) | | | |
| FTC (n = 23) | 102.4 (± 39.85) | | | |
| TFV (n = 24) | 10.0 (± 2.13) | | | |
| COBI (n = 15) | 25.0 (± 44.97) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Ctau of EVG, FTC, TFV, and COBI (Cohort 2)

| End point title | PK Parameter: Ctau of EVG, FTC, TFV, and COBI (Cohort 2)[20] |
|---|---|

End point description:

Ctau is defined as the observed drug concentration at the end of the dosing interval. Participants in the PK Substudy Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

(pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 8, and 24 hours post-dose at Week 4

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 23 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG | 370.0 (± 438.52) | | | |
| FTC | 114.9 (± 27.70) | | | |
| TFV | 15.1 (± 3.77) | | | |
| COBI | 96.0 (± 162.01) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Ctau of EVG, FTC, TFV, and COBI (Cohort 3)

| End point title | PK Parameter: Ctau of EVG, FTC, TFV, and COBI (Cohort 3)[21] |
|---|---|

End point description:

Ctau is defined as the observed drug concentration at the end of the dosing interval. Participants in the Intensive PK Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, and 8 hours post-dose at Week 2

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n = 22) | 277.5 (± 223.43) | | | |
| FTC (n = 27) | 82.5 (± 26.47) | | | |
| TFV (n = 27) | 11.4 (± 2.65) | | | |
| COBI (n = 18) | 23.0 (± 23.02) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Cmax of EVG, TAF, FTC, TFV, and COBI (Cohort 1)

| End point title | PK Parameter: Cmax of EVG, TAF, FTC, TFV, and COBI (Cohort 1)[22] |
|---|---|

End point description:

Cmax is defined as the maximum concentration of drug. Participants in the PK Substudy Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 5 minutes, 0.25, 0.5, 1, 1.5, 2, 4, 5, 8 and 24 hours post-dose at Week 4

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|---|---|---|---|---|
| EVG | 2229.6 (± 427.93) | | | |
| TAF | 166.8 (± 107.44) | | | |
| FTC | 2265.0 (± 510.55) | | | |
| TFV | 17.6 (± 4.18) | | | |
| COBI | 1202.4 (± 421.21) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Cmax of EVG, TAF, FTC, TFV, and COBI (Cohort 2)

| End point title | PK Parameter: Cmax of EVG, TAF, FTC, TFV, and COBI (Cohort 2)[23] |
|---|---|

End point description:

Cmax is defined as the maximum concentration of drug. Participants in the PK Substudy Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 8, and 24 hours post-dose at Week 4

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 23 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG | 3055.2 (± 1180.90) | | | |
| TAF | 313.3 (± 191.68) | | | |
| FTC | 3397.4 (± 916.06) | | | |
| TFV | 26.1 (± 5.43) | | | |
| COBI | 2079.4 (± 970.81) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Cmax of EVG, TAF, FTC, TFV, and COBI (Cohort 3)

| End point title | PK Parameter: Cmax of EVG, TAF, FTC, TFV, and COBI (Cohort 3)[24] |
|---|---|

End point description:

Cmax is defined as the maximum concentration of drug. Participants in the Intensive PK Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, and 8 hours post-dose at Week 2

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG | 3297.2 (± 1720.38) | | | |
| TAF | 286.6 (± 206.97) | | | |
| FTC | 3007.4 (± 1138.10) | | | |
| TFV | 19.6 (± 4.72) | | | |
| COBI | 1525.5 (± 788.12) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: CL/F of EVG and TAF (Cohort 1)

| End point title | PK Parameter: CL/F of EVG and TAF (Cohort 1)[25] |
|---|---|

End point description:

Apparent oral clearance (CL/F) is defined as the apparent clearance of the drug following oral administration. Participants in the PK Substudy Analysis Set with available data were analyzed

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 5 minutes, 0.25, 0.5, 1, 1.5, 2, 4, 5, 8 and 24 hours post-dose at Week 4

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: L/hr | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n=24) | 6.7 (± 1.74) | | | |
| TAF (n = 23) | 68.6 (± 52.64) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: CL/F of EVG and TAF (Cohort 2)

| End point title | PK Parameter: CL/F of EVG and TAF (Cohort 2)[26] |
|---|---|

End point description:

(CL/F) is defined as the apparent clearance of the drug following oral administration. Participants in the PK Substudy Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 8, and 24 hours post-dose at Week 4

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 22 | | | |
| Units: L/hr | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n = 22) | 6.3 (± 5.11) | | | |
| TAF (n = 11) | 31.9 (± 11.21) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: CL/F of EVG and TAF (Cohort 3)

| End point title | PK Parameter: CL/F of EVG and TAF (Cohort 3)[27] |
|---|---|

End point description:

CL/F is defined as the apparent clearance of the drug following oral administration. Participants in the Intensive PK Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, and 8 hours post-dose at Week 2

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: L/hr | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n = 24)<br>TAF (n = 17) | 3.4 (± 1.79)<br>18.5 (± 6.27) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Vz/F of EVG and TAF (Cohort 1)

| End point title | PK Parameter: Vz/F of EVG and TAF (Cohort 1)[28] |
|---|---|

End point description:

Vz/F is defined as the apparent volume of distribution of the drug after oral administration. Participants in the PK Substudy Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 5 minutes, 0.25, 0.5, 1, 1.5, 2, 4, 5, 8 and 24 hours post-dose at Week 4

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: liters | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n = 24) | 60.5 (± 18.77) | | | |
| TAF (n = 23) | 49.7 (± 32.54) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Vz/F of EVG and TAF (Cohort 2)

| End point title | PK Parameter: Vz/F of EVG and TAF (Cohort 2)[29] |
|---|---|

End point description:

Vz/F is defined as the apparent volume of distribution of the drug after oral administration. Participants in the PK Substudy Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 8, and 24 hours post-dose at Week 4

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| End point values | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 14 | | | |
| Units: liters | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n = 14) | 46.8 (± 36.02) | | | |
| TAF (n = 11) | 28.6 (± 25.74) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: Vz/F of EVG and TAF (Cohort 3)

| End point title | PK Parameter: Vz/F of EVG and TAF (Cohort 3)[30] |
|---|---|

End point description:

Vz/F is defined as the apparent volume of distribution of the drug after oral administration. Participants in the Intensive PK Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, and 8 hours post-dose at Week 2

Notes:

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 17 | | | |
| Units: liters | | | | |
| arithmetic mean (standard deviation) | | | | |
| EVG (n = 14) | 28.5 (± 28.30) | | | |
| TAF (n = 17) | 16.3 (± 11.07) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: AUCtau of FTC, TFV, and COBI (Cohort 1)

| End point title | PK Parameter: AUCtau of FTC, TFV, and COBI (Cohort 1)[31] |
|---|---|

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration versus time curve over the dosing interval). Participants in the PK Substudy Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 5 minutes, 0.25, 0.5, 1, 1.5, 2, 4, 5, 8 and 24 hours post-dose at Week 4

Notes:

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 24 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |

| | | | | |
|---|---|---|---|---|
| FTC (n = 24)<br>TFV (n = 23)<br>COBI (n = 23) | 14424.4 (± 3452.88)<br>287.6 (± 54.09)<br>8240.8 (± 2972.94) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: AUCtau of FTC, TFV, and COBI (Cohort 2)

| End point title | PK Parameter: AUCtau of FTC, TFV, and COBI (Cohort 2)[32] |
|---|---|

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration versus time curve over the dosing interval). Participants in the PK Substudy Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, 8, and 24 hours post-dose at Week 4

Notes:

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 23 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| FTC (n = 22)<br>TFV (n = 23)<br>COBI (n = 20) | 20629.2 (± 3906.01)<br>440.2 (± 92.13)<br>15890.7 (± 8208.78) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: PK Parameter: AUCtau of FTC, TFV, and COBI (Cohort 3)

| End point title | PK Parameter: AUCtau of FTC, TFV, and COBI (Cohort 3)[33] |
|---|---|

End point description:

AUCtau is defined as concentration of drug over time (the area under the concentration versus time curve over the dosing interval). Participants in the Intensive PK Analysis Set with available data were

analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

0 (pre-dose, ≤ 30 minutes prior to dosing), 0.25, 0.5, 1, 1.5, 2, 3, 4, 5, and 8 hours post-dose at Week 2

Notes:

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: hr*ng/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| FTC (n = 27) | 19468.1 (± 5635.74) | | | |
| TFV (n = 27) | 334.9 (± 76.77) | | | |
| COBI (n = 21) | 14485.2 (± 7166.10) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis[34] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. The Full analysis set included all participants who were enrolled in the study and had received at least 1 dose of study drug.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 90.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis[35] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 92.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis[36] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 Copies/mL at Week 24 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 94.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis[37] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 Copies/mL at Week 48 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |

| | | | | |
|---|---|---|---|---|
| number (not applicable) | 94.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis[38] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 100.0 (93.2 to 100.0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis[39] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 98.1 (89.7 to 100.0) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, as Defined by the FDA Snapshot Analysis[40] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 96.3 (81.0 to 99.9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis

| End point title | Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, as Defined by the FDA Snapshot Analysis[41] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed using the snapshot algorithm, which defines a participant's virologic response status using only the viral load at the predefined time point within an allowed window of time, along with study drug discontinuation status. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 96.3 (81.0 to 99.9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Failure Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Failure Analyses[42] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 90.0 (78.2 to 96.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Failure Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Failure Analyses[43] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[43] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 92.0 (80.8 to 97.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Failure Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Failure Analyses[44] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 94.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Failure Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Failure Analyses[45] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 copies/mL at Week 48 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 94.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Failure Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Failure Analyses[46] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Coho rt 2 only.

| End point values | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 100.0 (93.2 to 100.0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Failure Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Failure Analyses[47] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[47] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 100.0 (93.2 to 100.0) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Failure Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Failure Analyses[48] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 copies/mL at Week 24 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 100 | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Failure Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Failure Analyses[49] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 copies/mL at Week 48 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[49] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 100 | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Failure Analyses

| End point title | Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Failure Analyses[50] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 96.3 (81.0 to 99.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Failure Analyses

| End point title | Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Failure Analyses[51] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed based on missing = failure analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[51] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 96.3 (81.0 to 99.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Excluded Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Excluded Analyses[52] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 48 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 93.8 (82.8 to 98.7) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Excluded Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Excluded Analyses[53] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 48 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 95.8 (85.7 to 99.5) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Excluded Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Excluded Analyses[54] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 copies/mL at Week 24 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 48 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 97.9 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Excluded Analyses

| End point title | Cohort 1: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Excluded Analyses[55] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 copies/mL at Week 48 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 48 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 97.9 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Excluded Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Excluded Analyses[56] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 100.0 (93.2 to 100.0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Excluded Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Excluded Analyses[57] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[57] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 100.0 (93.2 to 100.0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Excluded Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 24, Based on Missing = Excluded Analyses[58] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 copies/mL at Week 24 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 100.0 | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Excluded Analyses

| End point title | Cohort 2: Percentage of Participants With Plasma HIV-1 RNA < 400 Copies/mL at Week 48, Based on Missing = Excluded Analyses[59] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 400 copies/mL at Week 48 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[59] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 100 | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Excluded Analyses

| End point title | Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 24, Based on Missing = Excluded Analyses[60] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 24 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 24

Notes:

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| End point values | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 96.3 (81.0 to 99.9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Excluded Analyses

| End point title | Cohort 3: Percentage of Participants With Plasma HIV-1 RNA < 50 Copies/mL at Week 48, Based on Missing = Excluded Analyses[61] |
|---|---|

End point description:

The percentage of participants with HIV-1 RNA < 50 copies/mL at Week 48 was analyzed based on missing = excluded analyses. Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Week 48

Notes:

[61] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| End point values | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of participants | | | | |
| number (confidence interval 95%) | 96.3 (81.0 to 99.9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Change From Baseline in Plasma log10 HIV-1 RNA at Week 24

| End point title | Cohort 1: Change From Baseline in Plasma log10 HIV-1 RNA at Week 24[62] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 24

Notes:

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: copies/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 50)<br>Change at Week 24 (n = 48) | 4.62 (± 0.587)<br>-3.25 (± 0.645) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Change From Baseline in Plasma log10 HIV-1 RNA at Week 48

| End point title | Cohort 1: Change From Baseline in Plasma log10 HIV-1 RNA at Week 48[63] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 48

Notes:

[63] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: copies/mL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 50) | 4.62 (± 0.587) | | | |
| Change at Week 48 (n = 48) | -3.26 (± 0.712) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Change From Baseline in CD4+ Cell Count at Week 24

| End point title | Cohort 1: Change From Baseline in CD4+ Cell Count at Week 24[64] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 24

Notes:

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: cells/µL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 50) | 471 (± 212.2) | | | |
| Change at Week 24 (n = 48) | 191 (± 175.2) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Change From Baseline in CD4+ Cell Count at Week 48

| End point title | Cohort 1: Change From Baseline in CD4+ Cell Count at Week 48[65] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 48

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: cells/µL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 50) | 471 (± 212.2) | | | |
| Change at Week 48 (n = 48) | 224 (± 170.3) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Change From Baseline in CD4+ Cell Count at Week 24

| End point title | Cohort 2: Change From Baseline in CD4+ Cell Count at Week 24[66] |
|---|---|

End point description:

Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 24

Notes:

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: cells/µL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 961 (± 275.5) | | | |
| Change at Week 24 | -118 (± 194.1) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Change From Baseline in CD4+ Cell Count at Week 48

| End point title | Cohort 2: Change From Baseline in CD4+ Cell Count at Week 48[67] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 48

Notes:

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: cells/µL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 52) | 961 (± 275.5) | | | |
| Change at Week 48 (n = 50) | -66 (± 203.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Change From Baseline in CD4+ Cell Count at Week 24

| End point title | Cohort 3: Change From Baseline in CD4+ Cell Count at Week 24[68] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 24

Notes:

[68] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: cells/µL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 27) | 1153 (± 459.9) | | | |
| Change at Week 24 (n = 17) | -137 (± 278.3) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Change From Baseline in CD4+ Cell Count at Week 48

| End point title | Cohort 3: Change From Baseline in CD4+ Cell Count at Week 48[69] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 48

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| End point values | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: cells/µL | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n =27) | 1153 (± 459.9) | | | |
| Change at Week 48 (n = 24) | -179 (± 319.2) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Change From Baseline in CD4+ Cell Percentage at Week 24

| End point title | Cohort 1: Change From Baseline in CD4+ Cell Percentage at Week 24[70] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 24

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| End point values | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of CD4+ cell | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 50) | 23.6 (± 8.80) | | | |
| Change at Week 24 (n = 48) | 7.7 (± 4.77) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 1: Change From Baseline in CD4+ Cell Percentage at Week 48

| End point title | Cohort 1: Change From Baseline in CD4+ Cell Percentage at Week 48[71] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 48

Notes:

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 1 only.

| **End point values** | Treatment Ph:Cohort 1: Age 12 to < 18 Years and Weight ≥ 35 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 50 | | | |
| Units: percentage of CD4+ cell | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 50) | 23.6 (± 8.80) | | | |
| Change at Week 48 (n = 47) | 9.3 (± 5.19) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Change From Baseline in CD4+ Cell Percentage at Week 24

| End point title | Cohort 2: Change From Baseline in CD4+ Cell Percentage at Week 24[72] |
|---|---|

End point description:

Participants in the Full Analysis Set were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 24

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of CD4+ cell | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline | 38.2 (± 6.44) | | | |
| Change at Week 24 | -0.8 (± 3.97) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 2: Change From Baseline in CD4+ Cell Percentage at Week 48

| End point title | Cohort 2: Change From Baseline in CD4+ Cell Percentage at Week 48[73] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 48

Notes:

[73] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 2 only.

| **End point values** | Treatment Ph: Cohort 2: Age 6 to < 12 Years and Weight ≥ 25 kg | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 52 | | | |
| Units: percentage of CD4+ cell | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 52) | 38.2 (± 6.44) | | | |
| Change at Week 48 (n = 50) | -0.6 (± 4.37) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Change From Baseline in CD4+ Cell Percentage at Week 24

| End point title | Cohort 3: Change From Baseline in CD4+ Cell Percentage at Week 24[74] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 24

Notes:

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of CD4+ cell | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 27) | 35.9 (± 6.73) | | | |
| Change at Week 24 (n = 17) | 0.0 (± 4.40) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Cohort 3: Change From Baseline in CD4+ Cell Percentage at Week 48

| End point title | Cohort 3: Change From Baseline in CD4+ Cell Percentage at Week 48[75] |
|---|---|

End point description:

Participants in the Full Analysis Set with available data were analyzed.

| End point type | Secondary |
|---|---|

End point timeframe:

Baseline, Week 48

Notes:

[75] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The end point is reporting statistics for Cohort 3 only.

| **End point values** | Treatment Ph:Cohort 3:Age ≥ 2 Years and Weight ≥ 14 to | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 27 | | | |
| Units: percentage of CD4+ cell | | | | |
| arithmetic mean (standard deviation) | | | | |
| Baseline (n = 27) | 35.9 (± 6.73) | | | |
| Change at Week 48 (n = 24) | 0.2 (± 3.78) | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to 583 Weeks

Adverse event reporting additional description:

The Safety Analysis Set included all participants who received at least 1 dose of study drug.

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 28.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | E/C/F/TAF Cohort 1: Age 12 to < 18 Years and Weight >= 35 kg |

Reporting group description:

Treatment naive adolescents (12 to < 18 years of age) with human immunodeficiency virus (HIV) received elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (E/C/F/TAF) (150/150/200/10 mg) fixed-dose combination (FDC) tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Reporting group title | E/C/F/TAF Cohort 3: Age >= 2 Years and Weight 14 to < 25 kg |

Reporting group description:

Children (≥ 2 years of age weighing ≥ 14 to < 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (90/90/120/6 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who attained a weight of ≥ 25 kg during the course of the study were switched to adult E/C/F/TAF (150/150/200/10 mg) tablets administered orally, once daily with food. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| | |
|---|---|
| Reporting group title | E/C/F/TAF Cohort 2: Age 6 to < 12 Years and Weight >= 25 kg |

Reporting group description:

hildren (6 to < 12 years of age weighing ≥ 25 kg) with HIV who were virologically suppressed received E/C/F/TAF (150/150/200/10 mg) FDC tablets, once daily orally with food for 48 weeks. Participants who completed 48 weeks of study treatment had the option to receive E/C/F/TAF in an extension phase of the study until: a) the participant turned 18 years old and E/C/F/TAF was commercially available for adults in the country in which the participant was enrolled; b) age-appropriate E/C/F/TAF became commercially available in participant's country.

| **Serious adverse events** | E/C/F/TAF Cohort 1: Age 12 to < 18 Years and Weight >= 35 kg | E/C/F/TAF Cohort 3: Age >= 2 Years and Weight 14 to < 25 kg | E/C/F/TAF Cohort 2: Age 6 to < 12 Years and Weight >= 25 kg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 10 / 50 (20.00%) | 1 / 27 (3.70%) | 7 / 52 (13.46%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Radius fracture | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Ulna fracture | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Neuralgia | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion missed | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Uveitis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Visual impairment | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Tonsillar hypertrophy | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Psychiatric disorders | | | |
| Suicide attempt | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Agitation | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute psychosis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Behaviour disorder | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bipolar I disorder | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Drug abuse | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Substance abuse | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |

| | | | |
|---|---|---|---|
| Glomerulonephritis acute | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary retention | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 1 / 27 (3.70%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abortion infected | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abscess limb | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 50 (2.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 5 %

| **Non-serious adverse events** | E/C/F/TAF Cohort 1: Age 12 to < 18 Years and Weight >= 35 kg | E/C/F/TAF Cohort 3: Age >= 2 Years and Weight 14 to < 25 kg | E/C/F/TAF Cohort 2: Age 6 to < 12 Years and Weight >= 25 kg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 47 / 50 (94.00%) | 25 / 27 (92.59%) | 45 / 52 (86.54%) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Anogenital warts | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Skin papilloma | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 1 / 27 (3.70%) | 0 / 52 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 2 / 27 (7.41%) | 3 / 52 (5.77%) |
| occurrences (all) | 3 | 2 | 4 |
| Reproductive system and breast disorders | | | |
| Heavy menstrual bleeding | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 4 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 4 / 27 (14.81%) | 5 / 52 (9.62%) |
| occurrences (all) | 0 | 4 | 9 |
| Cough | | | |
| subjects affected / exposed | 8 / 50 (16.00%) | 9 / 27 (33.33%) | 7 / 52 (13.46%) |
| occurrences (all) | 9 | 18 | 7 |
| Rhinorrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 6 / 52 (11.54%) |
| occurrences (all) | 4 | 0 | 6 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 1 / 27 (3.70%) | 2 / 52 (3.85%) |
| occurrences (all) | 3 | 1 | 3 |
| Nasal congestion | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 2 / 27 (7.41%) | 0 / 52 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 2 / 27 (7.41%) | 1 / 52 (1.92%) |
| occurrences (all) | 0 | 2 | 1 |
| Product issues | | | |
| Product size issue | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 5 | 0 | 1 |
| Investigations | | | |
| Weight decreased | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 1 / 27 (3.70%) | 0 / 52 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Injury, poisoning and procedural complications | | | |
| Skin abrasion | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 1 / 27 (3.70%) | 3 / 52 (5.77%) |
| occurrences (all) | 0 | 1 | 6 |
| Tooth fracture | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 0 / 27 (0.00%) | 3 / 52 (5.77%) |
| occurrences (all) | 0 | 0 | 3 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 14 / 50 (28.00%) | 1 / 27 (3.70%) | 8 / 52 (15.38%) |
| occurrences (all) | 18 | 1 | 8 |
| Somnolence | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |

| | | | |
|---|---|---|---|
| Dizziness | | | |
| subjects affected / exposed | 6 / 50 (12.00%) | 0 / 27 (0.00%) | 2 / 52 (3.85%) |
| occurrences (all) | 6 | 0 | 2 |
| Blood and lymphatic system disorders | | | |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 0 / 27 (0.00%) | 3 / 52 (5.77%) |
| occurrences (all) | 7 | 0 | 4 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 1 / 27 (3.70%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Eye disorders | | | |
| Visual impairment | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 12 / 50 (24.00%) | 4 / 27 (14.81%) | 13 / 52 (25.00%) |
| occurrences (all) | 14 | 4 | 13 |
| Diarrhoea | | | |
| subjects affected / exposed | 14 / 50 (28.00%) | 2 / 27 (7.41%) | 7 / 52 (13.46%) |
| occurrences (all) | 22 | 2 | 8 |
| Abdominal pain | | | |
| subjects affected / exposed | 11 / 50 (22.00%) | 0 / 27 (0.00%) | 10 / 52 (19.23%) |
| occurrences (all) | 12 | 0 | 10 |
| Dental caries | | | |
| subjects affected / exposed | 7 / 50 (14.00%) | 4 / 27 (14.81%) | 3 / 52 (5.77%) |
| occurrences (all) | 7 | 4 | 3 |
| Nausea | | | |
| subjects affected / exposed | 15 / 50 (30.00%) | 0 / 27 (0.00%) | 2 / 52 (3.85%) |
| occurrences (all) | 16 | 0 | 2 |
| Gastritis | | | |
| subjects affected / exposed | 7 / 50 (14.00%) | 0 / 27 (0.00%) | 2 / 52 (3.85%) |
| occurrences (all) | 7 | 0 | 2 |
| Constipation | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 3 / 27 (11.11%) | 4 / 52 (7.69%) |
| occurrences (all) | 5 | 4 | 4 |
| Abdominal pain upper | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 5 / 50 (10.00%) | 1 / 27 (3.70%) | 1 / 52 (1.92%) |
| occurrences (all) | 8 | 1 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Seborrhoeic dermatitis | | | |
| subjects affected / exposed | 7 / 50 (14.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 1 / 27 (3.70%) | 2 / 52 (3.85%) |
| occurrences (all) | 3 | 1 | 2 |
| Acne | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Renal and urinary disorders | | | |
| Leukocyturia | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 2 / 27 (7.41%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 2 / 52 (3.85%) |
| occurrences (all) | 3 | 0 | 2 |
| Pain in extremity | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 5 | 0 | 1 |
| Infections and infestations | | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 20 / 50 (40.00%) | 14 / 27 (51.85%) | 14 / 52 (26.92%) |
| occurrences (all) | 44 | 22 | 24 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 19 / 50 (38.00%) | 4 / 27 (14.81%) | 11 / 52 (21.15%) |
| occurrences (all) | 45 | 5 | 16 |
| Malaria | | | |
| subjects affected / exposed | 14 / 50 (28.00%) | 0 / 27 (0.00%) | 4 / 52 (7.69%) |
| occurrences (all) | 18 | 0 | 4 |

| | | | |
|---|---|---|---|
| Urinary tract infection | | | |
| subjects affected / exposed | 9 / 50 (18.00%) | 3 / 27 (11.11%) | 5 / 52 (9.62%) |
| occurrences (all) | 15 | 5 | 5 |
| Tonsillitis | | | |
| subjects affected / exposed | 6 / 50 (12.00%) | 5 / 27 (18.52%) | 3 / 52 (5.77%) |
| occurrences (all) | 7 | 10 | 3 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 5 / 27 (18.52%) | 2 / 52 (3.85%) |
| occurrences (all) | 3 | 10 | 2 |
| Body tinea | | | |
| subjects affected / exposed | 7 / 50 (14.00%) | 2 / 27 (7.41%) | 0 / 52 (0.00%) |
| occurrences (all) | 7 | 3 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 1 / 27 (3.70%) | 3 / 52 (5.77%) |
| occurrences (all) | 5 | 1 | 3 |
| Pneumonia | | | |
| subjects affected / exposed | 6 / 50 (12.00%) | 1 / 27 (3.70%) | 1 / 52 (1.92%) |
| occurrences (all) | 9 | 1 | 1 |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 2 / 27 (7.41%) | 2 / 52 (3.85%) |
| occurrences (all) | 2 | 2 | 2 |
| Pharyngitis | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 3 / 27 (11.11%) | 0 / 52 (0.00%) |
| occurrences (all) | 4 | 4 | 0 |
| Tinea capitis | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 2 / 27 (7.41%) | 4 / 52 (7.69%) |
| occurrences (all) | 2 | 2 | 4 |
| Covid-19 | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 1 / 27 (3.70%) | 3 / 52 (5.77%) |
| occurrences (all) | 3 | 1 | 3 |
| Vulvovaginal candidiasis | | | |
| subjects affected / exposed | 5 / 50 (10.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 9 | 0 | 1 |
| Conjunctivitis | | | |
| subjects affected / exposed | 4 / 50 (8.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 4 | 0 | 1 |

| | | | |
|---|---|---|---|
| Anal gonococcal infection | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 1 / 27 (3.70%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 1 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 2 / 27 (7.41%) | 0 / 52 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 1 / 52 (1.92%) |
| occurrences (all) | 4 | 0 | 1 |
| Folliculitis | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Nasal herpes | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 3 / 27 (11.11%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Hordeolum | | | |
| subjects affected / exposed | 3 / 50 (6.00%) | 0 / 27 (0.00%) | 0 / 52 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 2 / 27 (7.41%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Vulvovaginal mycotic infection | | | |
| subjects affected / exposed | 0 / 50 (0.00%) | 2 / 27 (7.41%) | 0 / 52 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite | | | |
| subjects affected / exposed | 2 / 50 (4.00%) | 4 / 27 (14.81%) | 0 / 52 (0.00%) |
| occurrences (all) | 2 | 5 | 0 |
| Vitamin D deficiency | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed<br>occurrences (all) | 8 / 50 (16.00%)<br>8 | 0 / 27 (0.00%)<br>0 | 3 / 52 (5.77%)<br>3 |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 22 March 2013 | - Corrected the measurement unit for the CD4 cell count inclusion criterion<br>- Increased the minimum number of participants in each age subgroup of Part A<br>- Added a 24-hour time point to the intensive PK sampling times<br>- Updated the list of disallowed and discouraged medications in the study |
| 09 January 2015 | - Added palatability and acceptability assessment procedures<br>- Added Cohort 2 Part A with virologically suppressed children 6 to < 12 years of age weighing ≥ 25 kg |
| 11 August 2016 | - Added Cohort 2 Part B with virologically suppressed children 6 to < 12 years of age weighing ≥ 25 kg |
| 11 June 2018 | Added Cohort 3, to comprise virologically suppressed, HIV-1 infected children ≥ 2 years of age and weighing ≥ 14 to < 25 kg, in which to allow evaluation of the PK, safety, efficacy, and tolerability of the E/C/F/TAF low dose tablet (E/C/F/TAF 90/90/120/6 mg). |
| 17 August 2018 | Updated CD4 cell inclusion criteria for Cohort 3, and added time points for palatability and acceptability assessments. |
| 21 February 2020 | Clarified that fasting was not required in advance of sample collection for evaluation of urine renal safety parameters and serum bone safety parameters. |
| 02 June 2021 | Clarified subject study visits during extension phase of the study; and added text to distinguish between E/C/F/TAF STR and E/C/F/TAF LD STR where applicable. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

### Online references

http://www.ncbi.nlm.nih.gov/pubmed/30169223

http://www.ncbi.nlm.nih.gov/pubmed/27765666