Clinical trial results:
A Phase 1, Single-Dose, Cross-Over Study Evaluating the Relative Bioavailability and Food Effect of the Bictegravir/Emtricitabine/Tenofovir Alafenamide and Emtricitabine/Tenofovir Alafenamide Pediatric Tablets for Oral Suspension as Compared with the Adult-Strength Tablets

Summary

EudraCT number	2021-000436-62
Trial protocol	Outside EU/EEA
Global end of trial date	24 November 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	GS-US-380-4547

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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-001766-PIP01-15
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 November 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 November 2021
Global end of trial reached?	Yes
Global end of trial date	24 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study were to evaluate:
- The relative bioavailability of a bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) fixed-dose combination (FDC) pediatric tablet for oral suspension formulation relative to the adult B/F/TAF FDC tablet formulation
- The bioequivalence of a emtricitabine/tenofovir alafenamide (F/TAF) FDC pediatric tablet for oral suspension formulation relative to the B/F/TAF FDC pediatric tablet for oral suspension formulation
- The relative bioavailability of F/TAF FDC pediatric tablet for oral suspension formulations relative to the adult F/TAF FDC tablet formulation

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	19 July 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 248
Worldwide total number of subjects	248
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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	248
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were enrolled at study sites in the United States.

Pre-assignment

Screening details:

539 participants were screened.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort 1: Treatment Sequence ABC

Arm description:

Participants received treatment A (a single dose of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 1, followed by treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment C (a single dose of emtricitabine/tenofovir alafenamide (F/TAF) 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	B/F/TAF 50/200/25 mg
Investigational medicinal product code	
Other name	Biktarvy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered as a single dose

Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 50/6.25 mg tablets for oral suspension formulation administered as a single dose

Arm title	Cohort 1: Treatment Sequence ACB

Arm description:

Participants received treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 1, followed by treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on

Day 10 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	B/F/TAF 50/200/25 mg
Investigational medicinal product code	
Other name	Biktarvy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered as a single dose

Investigational medicinal product name	F/TAF 50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose

Arm title	Cohort 1: Treatment Sequence BAC

Arm description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatmnent A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 10 and then treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 50/200/25 mg
Investigational medicinal product code	
Other name	Biktarvy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered as a single dose

Investigational medicinal product name	F/TAF 50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 50/6.25 mg tablets for oral suspension formulation administered as a single dose

Arm title	Cohort 1: Treatment Sequence BCA

Arm description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 50/200/25 mg
Investigational medicinal product code	
Other name	Biktarvy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered as a single dose

Arm title	Cohort 1: Treatment Sequence CAB

Arm description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 10 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 50/200/25 mg
Investigational medicinal product code	
Other name	Biktarvy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered as a single dose

Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose

Arm title	Cohort 1: Treatment Sequence CBA

Arm description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 1 followed by treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 10, and then treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 50/200/25 mg
Investigational medicinal product code	
Other name	Biktarvy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Administered as a single dose

Arm title	Cohort 2: Treatment Sequence BD

Arm description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Day 1 and then treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Day 12. There was a 10-day washout between each treatment.

Arm type	Experimental

Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose under fasted conditions

Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose under fed conditions

Arm title	Cohort 2: Treatment Sequence DB

Arm description:

Participants received treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Day 1 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Day 12. There was a 10-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose under fed conditions

Investigational medicinal product name	B/F/TAF 12.5/50/6.25 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 × 12.5/50/6.25 mg tablets for oral suspension formulation administered as a single dose under fasted conditions

Arm title	Cohort 3: Treatment Sequence EFG

Arm description:

Participants received treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then Treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	B/F/TAF 15/60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

15/60/7.5 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/11 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/11 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 3: Treatment Sequence EGF

Arm description:

Participants received treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	B/F/TAF 15/60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

15/60/7.5 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/11 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/11 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 3: Treatment Sequence FEG

Arm description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 15/60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

15/60/7.5 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/11 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/11 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 3: Treatment Sequence FGE

Arm description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension formulation orally under fasted conditions) on Day 10 and then treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/11 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/11 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 15/60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

15/60/7.5 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 3: Treatment Sequence GEF

Arm description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 60/11 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/11 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 15/60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

15/60/7.5 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 3: Treatment Sequence GFE

Arm description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension formulation orally under fasted conditions) on Day 10 and then treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 60/11 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/11 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	B/F/TAF 15/60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet

Routes of administration	Oral use

Dosage and administration details:

15/60/7.5 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 4: Treatment Sequence FHI

Arm description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 10 and the treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 200/25 mg
Investigational medicinal product code	
Other name	Descovy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200/25 mg tablet administered as a single dose

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 4: Treatment Sequence FIH

Arm description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 10 and then treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment..

Arm type	Experimental
Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet

Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 200/25 mg
Investigational medicinal product code	
Other name	Descovy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200/25 mg tablet administered as a single dose

Arm title	Cohort 4: Treatment Sequence HFI

Arm description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 200/25 mg
Investigational medicinal product code	
Other name	Descovy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200/25 mg tablet administered as a single dose

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 4: Treatment Sequence HIF

Arm description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 1, followed by treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 200/25 mg
Investigational medicinal product code	
Other name	Descovy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details: 200/25 mg tablet administered as a single dose	
Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 60/7.5 mg tablet for oral suspension formulation administered as a single dose	
Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 60/10 mg tablet for oral suspension formulation administered as a single dose	
Arm title	Cohort 4: Treatment Sequence IFH
Arm description: Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.	
Arm type	Experimental
Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 60/7.5 mg tablet for oral suspension formulation administered as a single dose	
Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 60/10 mg tablet for oral suspension formulation administered as a single dose	
Investigational medicinal product name	F/TAF 200/25 mg
Investigational medicinal product code	
Other name	Descovy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details: 200/25 mg tablet administered as a single dose	
Arm title	Cohort 4: Treatment Sequence IHF
Arm description: Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 1, followed by treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.	
Arm type	Experimental

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose

Investigational medicinal product name	F/TAF 200/25 mg
Investigational medicinal product code	
Other name	Descovy®
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

200/25 mg tablet administered as a single dose

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose

Arm title	Cohort 5: Treatment Sequence JK

Arm description:

Participants received treatment J [a single dose of F/TAF (60/10 mg or 60/7.5 mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fasted conditions] on Day 1 and then treatment K [a single dose of F/TAF (60/10 mg or 60/7.5 mg) pediatric tablet for oral single dose pension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fed conditions] on Day 13. There was a 6-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose under fed conditions

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose under fasted conditions

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose under fasted conditions

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose under fed conditions

Arm title	Cohort 5: Treatment Sequence KJ

Arm description:

Participants received treatment K [a single dose of F/TAF (60/10 mg or 60/7.5mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fed conditions] on Day 1 and then treatment J [a single dose of F/TAF (60/10 mg or 60/7.5mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fasted conditions] on Day 13. There was a 6-day washout between each treatment.

Arm type	Experimental
Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose under fasted conditions

Investigational medicinal product name	F/TAF 60/10 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/10 mg tablet for oral suspension formulation administered as a single dose under fed conditions

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose under fed conditions

Investigational medicinal product name	F/TAF 60/7.5 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

60/7.5 mg tablet for oral suspension formulation administered as a single dose under fasted conditions

Number of subjects in period 1	Cohort 1: Treatment Sequence ABC	Cohort 1: Treatment Sequence ACB	Cohort 1: Treatment Sequence BAC
Started	16	16	16
Completed	16	16	16
Not completed	0	0	0
Protocol violation	-	-	-
Withdrew consent	-	-	-

Number of subjects in period 1	Cohort 1: Treatment Sequence BCA	Cohort 1: Treatment Sequence CAB	Cohort 1: Treatment Sequence CBA
Started	16	16	16
Completed	16	16	16
Not completed	0	0	0
Protocol violation	-	-	-
Withdrew consent	-	-	-

Number of subjects in period 1	Cohort 2: Treatment Sequence BD	Cohort 2: Treatment Sequence DB	Cohort 3: Treatment Sequence EFG
Started	18	18	11
Completed	18	18	10
Not completed	0	0	1
Protocol violation	-	-	-
Withdrew consent	-	-	1

Number of subjects in period 1	Cohort 3: Treatment Sequence EGF	Cohort 3: Treatment Sequence FEG	Cohort 3: Treatment Sequence FGE
Started	11	11	11
Completed	11	10	11
Not completed	0	1	0
Protocol violation	-	1	-
Withdrew consent	-	-	-

Number of subjects in period 1	Cohort 3: Treatment Sequence GEF	Cohort 3: Treatment Sequence GFE	Cohort 4: Treatment Sequence FHI
Started	11	11	5
Completed	11	11	5
Not completed	0	0	0
Protocol violation	-	-	-
Withdrew consent	-	-	-

Number of subjects in period 1	Cohort 4: Treatment Sequence FIH	Cohort 4: Treatment Sequence HFI	Cohort 4: Treatment Sequence HIF
Started	5	5	5
Completed	5	5	5
Not completed	0	0	0
Protocol violation	-	-	-
Withdrew consent	-	-	-

Number of subjects in period 1	Cohort 4: Treatment	Cohort 4: Treatment	Cohort 5: Treatment

	Sequence IFH	Sequence IHF	Sequence JK
Started	5	5	10
Completed	4	5	10
Not completed	1	0	0
Protocol violation	-	-	-
Withdrew consent	1	-	-

Number of subjects in period 1	Cohort 5: Treatment Sequence KJ
Started	10
Completed	10
Not completed	0
Protocol violation	-
Withdrew consent	-

Baseline characteristics

Reporting groups

Reporting group title	Cohort 1: Treatment Sequence ABC

Reporting group description:

Participants received treatment A (a single dose of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 1, followed by treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment C (a single dose of emtricitabine/tenofovir alafenamide (F/TAF) 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence ACB

Reporting group description:

Participants received treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 1, followed by treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence BAC

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatmnent A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 10 and then treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence BCA

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence CAB

Reporting group description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 10 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence CBA

Reporting group description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 1 followed by treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 10, and then treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 2: Treatment Sequence BD

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Day 1 and then treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Day 12. There was a 10-day washout between each treatment.

Reporting group title	Cohort 2: Treatment Sequence DB

Reporting group description:

Participants received treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Day 1 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Day 12. There was a 10-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence EFG

Reporting group description:

Participants received treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then Treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence EGF

Reporting group description:

Participants received treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence FEG

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence FGE

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension formulation orally under fasted conditions) on Day 10 and then treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence GEF

Reporting group description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence GFE

Reporting group description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension formulation orally under fasted conditions) on Day 10 and then treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence FHI

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 10 and the treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence FIH

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 10 and then treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment..

Reporting group title	Cohort 4: Treatment Sequence HFI

Reporting group description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence HIF

Reporting group description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 1, followed by treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence IFH

Reporting group description:

Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence IHF

Reporting group description:

Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 1, followed by treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 5: Treatment Sequence JK

Reporting group description:

Participants received treatment J [a single dose of F/TAF (60/10 mg or 60/7.5 mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fasted conditions] on Day 1 and then treatment K [a single dose of F/TAF (60/10 mg or 60/7.5 mg) pediatric tablet for oral single dose pension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fed conditions] on Day 13. There was a 6-day washout between each treatment.

Reporting group title	Cohort 5: Treatment Sequence KJ

Reporting group description:

Participants received treatment K [a single dose of F/TAF (60/10 mg or 60/7.5mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fed conditions] on Day 1 and then treatment J [a single dose of F/TAF (60/10 mg or 60/7.5mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fasted conditions] on Day 13. There was a 6-day washout between each treatment.

Reporting group values	Cohort 1: Treatment Sequence ABC	Cohort 1: Treatment Sequence ACB	Cohort 1: Treatment Sequence BAC
Number of subjects	16	16	16
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	34	28	34
standard deviation	± 4.7	± 5.7	± 7.1
Gender categorical			
Units: Subjects			
Female	5	6	5
Male	11	10	11

Race Units: Subjects			
American Indian or Alaska Native	1	2	0
Asian	1	0	0
Black	7	10	6
Native Hawaiian or Pacific Islander	0	0	0
White	7	4	8
Other	0	0	2
Ethnicity Units: Subjects			
Hispanic or Latino	7	3	6
Not Hispanic or Latino	9	13	10

Reporting group values	Cohort 1: Treatment Sequence BCA	Cohort 1: Treatment Sequence CAB	Cohort 1: Treatment Sequence CBA
Number of subjects	16	16	16
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	37	33	33
standard deviation	± 4.6	± 6.6	± 7.7
Gender categorical Units: Subjects			
Female	4	8	7
Male	12	8	9
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black	7	10	11
Native Hawaiian or Pacific Islander	0	1	0
White	9	5	5
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	4	4	4
Not Hispanic or Latino	12	12	12

Reporting group values	Cohort 2: Treatment Sequence BD	Cohort 2: Treatment Sequence DB	Cohort 3: Treatment Sequence EFG
Number of subjects	18	18	11
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	32	33	32
standard deviation	± 7.1	± 7.2	± 5.6

Gender categorical Units: Subjects			
Female	11	6	5
Male	7	12	6
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black	7	9	5
Native Hawaiian or Pacific Islander	2	0	0
White	9	7	6
Other	0	2	0
Ethnicity Units: Subjects			
Hispanic or Latino	9	7	4
Not Hispanic or Latino	9	11	7

Reporting group values	Cohort 3: Treatment Sequence EGF	Cohort 3: Treatment Sequence FEG	Cohort 3: Treatment Sequence FGE
Number of subjects	11	11	11
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	29	33	33
standard deviation	± 6.5	± 6.7	± 5.2
Gender categorical Units: Subjects			
Female	5	1	3
Male	6	10	8
Race Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	0	2	0
Black	5	3	4
Native Hawaiian or Pacific Islander	1	0	0
White	4	6	6
Other	1	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	3	4	4
Not Hispanic or Latino	8	7	7

Reporting group values	Cohort 3: Treatment Sequence GEF	Cohort 3: Treatment Sequence GFE	Cohort 4: Treatment Sequence FHI
Number of subjects	11	11	5
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	28	37	32
standard deviation	± 7.4	± 5.8	± 9.3
Gender categorical Units: Subjects			
Female	2	5	2
Male	9	6	3
Race Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	1	0	0
Black	3	5	0
Native Hawaiian or Pacific Islander	0	0	0
White	6	6	5
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	5	3	5
Not Hispanic or Latino	6	8	0

Reporting group values	Cohort 4: Treatment Sequence FIH	Cohort 4: Treatment Sequence HFI	Cohort 4: Treatment Sequence HIF
Number of subjects	5	5	5
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	37	38	35
standard deviation	± 1.1	± 5.3	± 6.3
Gender categorical Units: Subjects			
Female	3	2	4
Male	2	3	1
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black	0	3	1
Native Hawaiian or Pacific Islander	0	0	0
White	5	2	4
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	5	5	5
Not Hispanic or Latino	0	0	0

Reporting group values	Cohort 4: Treatment Sequence IFH	Cohort 4: Treatment Sequence IHF	Cohort 5: Treatment Sequence JK
Number of subjects	5	5	10

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	32	33	36
standard deviation	± 4.8	± 5.9	± 7.8
Gender categorical Units: Subjects			
Female	2	2	4
Male	3	3	6
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black	1	0	4
Native Hawaiian or Pacific Islander	0	0	0
White	4	5	6
Other	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	5	5	10
Not Hispanic or Latino	0	0	0

Reporting group values	Cohort 5: Treatment Sequence KJ	Total	
Number of subjects	10	248	
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	36		
standard deviation	± 6.4	-	
Gender categorical Units: Subjects			
Female	4	96	
Male	6	152	
Race Units: Subjects			
American Indian or Alaska Native	0	5	
Asian	0	4	
Black	1	102	
Native Hawaiian or Pacific Islander	0	4	
White	9	128	
Other	0	5	
Ethnicity Units: Subjects			
Hispanic or Latino	9	116	
Not Hispanic or Latino	1	132	

End points reporting groups

Reporting group title	Cohort 1: Treatment Sequence ABC

Reporting group description:

Participants received treatment A (a single dose of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 1, followed by treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment C (a single dose of emtricitabine/tenofovir alafenamide (F/TAF) 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence ACB

Reporting group description:

Participants received treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 1, followed by treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence BAC

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatmnent A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 10 and then treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence BCA

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 10 and then treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence CAB

Reporting group description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 1, followed by treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 10 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 1: Treatment Sequence CBA

Reporting group description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Day 1 followed by treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Day 10, and then treatment A (a single dose of B/F/TAF 50/200/25 mg adult tablet (1 × 50/200/25 mg tablet) orally under fasted condition) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 2: Treatment Sequence BD

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Day 1 and then treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Day 12. There was a 10-day washout between each treatment.

Reporting group title	Cohort 2: Treatment Sequence DB

Reporting group description:

Participants received treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Day 1 and then treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Day 12. There was a 10-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence EFG

Reporting group description:

Participants received treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then Treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence EGF

Reporting group description:

Participants received treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence FEG

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence FGE

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension formulation orally under fasted conditions) on Day 10 and then treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence GEF

Reporting group description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 3: Treatment Sequence GFE

Reporting group description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension formulation orally under fasted conditions) on Day 10 and then treatment E (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence FHI

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 10 and the treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence FIH

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 1, followed by treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 10 and then treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment..

Reporting group title	Cohort 4: Treatment Sequence HFI

Reporting group description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence HIF

Reporting group description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 1, followed by treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence IFH

Reporting group description:

Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 1, followed by treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 10 and then treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 4: Treatment Sequence IHF

Reporting group description:

Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Day 1, followed by treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Day 10 and then treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Day 19. There was a 8-day washout between each treatment.

Reporting group title	Cohort 5: Treatment Sequence JK

Reporting group description:

Participants received treatment J [a single dose of F/TAF (60/10 mg or 60/7.5 mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fasted conditions] on Day 1 and then treatment K [a single dose of F/TAF (60/10 mg or 60/7.5 mg) pediatric tablet for oral single dose pension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fed conditions] on Day 13. There was a 6-day washout between each treatment.

Reporting group title	Cohort 5: Treatment Sequence KJ

Reporting group description:

Participants received treatment K [a single dose of F/TAF (60/10 mg or 60/7.5mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fed conditions] on Day 1 and then treatment J [a single dose of F/TAF (60/10 mg or 60/7.5mg) pediatric tablet for oral suspension (1 × 60/10 mg or 1 × 60/7.5mg tablet) orally under fasted conditions] on Day 13. There was a 6-day washout between each treatment.

Subject analysis set title	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment A (a single of B/F/TAF 50/200/25 mg adult tablet (1× 50/200/25 mg tablet) orally under fasted condition) on Days 1, 10, or 19 according to the treatment sequence for Cohort 1.

Subject analysis set title	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Days 1, 10, or 19 according to the treatment sequence for Cohort 1.

Subject analysis set title	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Days 1, 10, or 19 according to the treatment sequence for Cohort 1.

Subject analysis set title	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Days 1 or 12 according to the treatment sequence for Cohort 2.

Subject analysis set title	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Days 1, or 12 according to the treatment sequence for Cohort 2.

Subject analysis set title	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment F (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 3.

Subject analysis set title	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 3.

Subject analysis set title	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 3.

Subject analysis set title	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence under Cohort 4.

Subject analysis set title	Cohort 4 H (F/TAF 200/25 mg adult tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 4.

Subject analysis set title	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Days 1, 10 , or 19 according to the treatment sequence for Cohort 4.

Subject analysis set title	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment J (a single dose of F/TAF (60/10 mg) pediatric tablet for oral suspension (1 × 60/10 mg tablet) orally under fasted conditions) on Days 1 or 13 according to the treatment

sequence for Cohort 5.

Subject analysis set title	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received treatment K (a single dose of F/TAF (60/10 mg) pediatric tablet for oral suspension (1 × 60/10 mg tablet) orally under fed conditions) on Days 1, or 13 according to the treatment sequence for Cohort 5.

Primary: Cohorts 1 and 3: Pharmacokinetic (PK) Parameter of Bictegravir (BIC): Area Under the Plasma Concentration Versus Time Curve From Time Zero to the Last Quantifiable Concentration (AUClast)

End point title	Cohorts 1 and 3: Pharmacokinetic (PK) Parameter of Bictegravir (BIC): Area Under the Plasma Concentration Versus Time Curve From Time Zero to the Last Quantifiable Concentration (AUClast)[1]

End point description:

PK analysis set included all randomized participants who took at least 1 dose of study drug and had at least 1 non-missing post dose concentration value reported by the PK laboratory for the corresponding analyte.

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	96	96	66	
Units: hours*nanograms per milliliter (h*ng/mL)				
arithmetic mean (standard deviation)	109596.7 (± 28725.05)	131863.9 (± 28769.05)	37472.7 (± 6921.35)	

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1 and 3: PK Parameter of BIC: Area Under the Plasma Concentration Versus Time Curve From Time Zero to Infinity (AUCinf)

End point title	Cohorts 1 and 3: PK Parameter of BIC: Area Under the Plasma Concentration Versus Time Curve From Time Zero to Infinity (AUCinf)[2]

End point description:

Participants in the PK Analysis Set were analyzed.

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours

postdose on Days 1, 10, or 19

Notes:

[2] - 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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	96	96	66	
Units: h*ng/mL				
arithmetic mean (standard deviation)	111101.0 (± 29305.00)	133655.1 (± 29773.87)	38684.8 (± 7403.16)	

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1 and 3: PK Parameter of BIC: Maximum Observed Plasma Concentration of Drug (Cmax)

End point title	Cohorts 1 and 3: PK Parameter of BIC: Maximum Observed Plasma Concentration of Drug (Cmax)[3]

End point description:

Participants in the PK Analysis Set were analyzed.

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

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: No statistical comparison was planned or performed.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	96	96	66	
Units: nanograms per milliliter (ng/mL)				
arithmetic mean (standard deviation)	5607.5 (± 1275.94)	8230.1 (± 1444.72)	2443.6 (± 420.41)	

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1, 3 and 4: PK Parameter of Emtricitabine (FTC): AUClast

End point title	Cohorts 1, 3 and 4: PK Parameter of Emtricitabine (FTC): AUClast[4]

End point description:

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

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

Notes:

[4] - 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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	66
Units: h*ng/mL				
arithmetic mean (standard deviation)	11504.4 (± 1787.45)	10674.8 (± 2181.88)	10566.6 (± 1688.08)	3110.0 (± 530.30)

End point values	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	65	64	29	29
Units: h*ng/mL				
arithmetic mean (standard deviation)	3144.2 (± 596.18)	3163.3 (± 530.28)	2740.3 (± 558.89)	9946.9 (± 2016.40)

End point values	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: h*ng/mL				
arithmetic mean (standard deviation)	2734.0 (± 520.08)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1, 3 and 4: PK Parameter of FTC: AUCinf

End point title	Cohorts 1, 3 and 4: PK Parameter of FTC: AUCinf[5]

End point description:

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

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	63
Units: h*ng/mL				
arithmetic mean (standard deviation)	11804.1 (± 1794.57)	11009.5 (± 2257.20)	10918.5 (± 1729.34)	3219.5 (± 541.61)

End point values	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	63	59	29	29
Units: h*ng/mL				
arithmetic mean (standard deviation)	3294.1 (± 607.17)	3304.9 (± 541.68)	2843.1 (± 563.36)	10143.8 (± 2041.22)

End point values	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)			
Subject group type	Subject analysis set			
Number of subjects analysed	29			
Units: h*ng/mL				
arithmetic mean (standard deviation)	2834.5 (± 546.21)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1, 3 and 4: PK Parameter of FTC: Cmax

End point title	Cohorts 1, 3 and 4: PK Parameter of FTC: Cmax[6]

End point description:

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

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

Notes:

[6] - 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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	66
Units: ng/mL				
arithmetic mean (standard deviation)	2340.7 (± 644.56)	1932.8 (± 382.02)	1895.0 (± 388.20)	685.4 (± 163.86)

End point values	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	65	64	29	29
Units: ng/mL				
arithmetic mean (standard deviation)	663.1 (± 168.49)	671.7 (± 146.60)	635.2 (± 139.60)	2268.3 (± 599.63)

End point values	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)			

Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: ng/mL				
arithmetic mean (standard deviation)	619.1 (± 148.66)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1, 3 and 4: PK Parameter of Tenofovir Alafenamide (TAF): AUClast

End point title	Cohorts 1, 3 and 4: PK Parameter of Tenofovir Alafenamide (TAF): AUClast[7]

End point description:

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

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	66
Units: h*ng/mL				
arithmetic mean (standard deviation)	221.1 (± 124.56)	229.9 (± 130.07)	161.2 (± 80.93)	49.0 (± 23.47)

End point values	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	65	64	29	29
Units: h*ng/mL				
arithmetic mean (standard deviation)	51.6 (± 23.81)	56.0 (± 23.65)	67.7 (± 34.10)	214.8 (± 133.66)

End point values	Cohort 4 I (F/TAF 60/7.5 mg pediatric			

	tablet)			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: h*ng/mL				
arithmetic mean (standard deviation)	51.3 (± 28.43)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1, 3 and 4: PK Parameter of TAF: AUCinf

End point title	Cohorts 1, 3 and 4: PK Parameter of TAF: AUCinf[8]

End point description:

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

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

Notes:

[8] - 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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	66
Units: h*ng/mL				
arithmetic mean (standard deviation)	222.6 (± 124.62)	231.3 (± 130.11)	162.7 (± 80.89)	50.1 (± 23.64)

End point values	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	65	63	29	28
Units: h*ng/mL				
arithmetic mean (standard deviation)	52.8 (± 24.22)	57.4 (± 23.78)	68.8 (± 34.33)	215.8 (± 136.03)

End point values	Cohort 4 I (F/TAF 60/7.5 mg pediatric			

	tablet)			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: h*ng/mL				
arithmetic mean (standard deviation)	52.9 (± 28.49)			

Statistical analyses

No statistical analyses for this end point

Primary: Cohorts 1, 3 and 4: PK Parameter of TAF: Cmax

End point title	Cohorts 1, 3 and 4: PK Parameter of TAF: Cmax[9]

End point description:

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

End point type	Primary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1, 10, or 19

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.

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	66
Units: ng/mL				
arithmetic mean (standard deviation)	325.9 (± 205.18)	341.9 (± 153.36)	233.2 (± 111.77)	85.7 (± 35.15)

End point values	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	65	64	29	29
Units: ng/mL				
arithmetic mean (standard deviation)	79.1 (± 32.25)	90.1 (± 35.79)	116.1 (± 60.75)	333.1 (± 210.10)

End point values	Cohort 4 I (F/TAF 60/7.5			

	mg pediatric tablet)			
Subject group type	Subject analysis set			
Number of subjects analysed	30			
Units: ng/mL				
arithmetic mean (standard deviation)	79.7 (± 39.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: PK Parameter of BIC: AUClast

End point title	Cohort 2: PK Parameter of BIC: AUClast

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: h*ng/mL				
arithmetic mean (standard deviation)	128870.5 (± 29350.20)	120261.5 (± 28446.78)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: PK Parameter of BIC: AUCinf

End point title	Cohort 2: PK Parameter of BIC: AUCinf

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: h*ng/mL				
arithmetic mean (standard deviation)	130472.1 (± 30598.63)	121724.3 (± 29263.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: PK Parameter of BIC: Cmax

End point title	Cohort 2: PK Parameter of BIC: Cmax

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: ng/mL				
arithmetic mean (standard deviation)	8345.6 (± 1303.45)	4889.1 (± 851.69)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: PK Parameter of FTC: AUClast

End point title	Cohort 2: PK Parameter of FTC: AUClast

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: h*ng/mL				
arithmetic mean (standard deviation)	10369.5 (± 1882.89)	10197.5 (± 1796.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohorts 2 : PK Parameter of FTC: AUCinf

End point title	Cohorts 2 : PK Parameter of FTC: AUCinf

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 and 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: h*ng/mL				
arithmetic mean (standard deviation)	10698.1 (± 1902.11)	10490.3 (± 1780.50)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohorts 2 : PK Parameter of FTC: Cmax

End point title	Cohorts 2 : PK Parameter of FTC: Cmax

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: ng/mL				
arithmetic mean (standard deviation)	1996.7 (± 450.23)	1384.7 (± 336.01)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2: PK Parameter of TAF: AUClast

End point title	Cohort 2: PK Parameter of TAF: AUClast

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: h*ng/mL				

arithmetic mean (standard deviation)	205.2 (± 79.19)	244.5 (± 85.10)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2 : PK Parameter of TAF: AUCinf

End point title	Cohort 2 : PK Parameter of TAF: AUCinf

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: h*ng/mL				
arithmetic mean (standard deviation)	206.6 (± 79.30)	248.9 (± 84.28)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 2 : PK Parameter of TAF: Cmax

End point title	Cohort 2 : PK Parameter of TAF: Cmax

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 12

End point values	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	35		
Units: ng/mL				
arithmetic mean (standard deviation)	365.7 (± 131.98)	153.7 (± 88.75)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 5: PK Parameter of FTC: AUClast

End point title	Cohort 5: PK Parameter of FTC: AUClast

End point description:

Participants in the PK Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 8

End point values	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: h*ng/mL				
arithmetic mean (standard deviation)	2689.5 (± 408.26)	2595.0 (± 366.73)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohorts 5: PK Parameter of FTC: AUCinf

End point title	Cohorts 5: PK Parameter of FTC: AUCinf

End point description:

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

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 8

End point values	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	18	20		
Units: h*ng/mL				
arithmetic mean (standard deviation)	2792.8 (± 437.50)	2718.0 (± 386.90)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 5: PK Parameter of FTC: Cmax

End point title	Cohort 5: PK Parameter of FTC: Cmax

End point description:

Participants in the PK Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 8

End point values	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: ng/mL				
arithmetic mean (standard deviation)	588.9 (± 155.98)	350.1 (± 68.74)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 5: PK Parameter of TAF: AUClast

End point title	Cohort 5: PK Parameter of TAF: AUClast

End point description:

Participants in the PK Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 8

End point values	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: h*ng/mL				
arithmetic mean (standard deviation)	68.5 (± 24.73)	104.0 (± 35.85)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 5: PK Parameter of TAF: AUCinf

End point title	Cohort 5: PK Parameter of TAF: AUCinf

End point description:

Participants in the PK Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 8

End point values	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: h*ng/mL				
arithmetic mean (standard deviation)	69.6 (± 24.94)	106.4 (± 35.31)		

Statistical analyses

No statistical analyses for this end point

Secondary: Cohort 5: PK Parameter of TAF: Cmax

End point title	Cohort 5: PK Parameter of TAF: Cmax

End point description:

Participants in the PK Analysis Set were analyzed.

End point type	Secondary

End point timeframe:

Predose (≤ 5 min), 5 min, 0.25, 0.5, 0.75, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36, 48, 72, 96, and 120 hours postdose on Days 1 or 8

End point values	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20	20		
Units: ng/mL				
arithmetic mean (standard deviation)	105.2 (± 49.10)	50.6 (± 23.51)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Experienced Treatment-emergent Adverse Events (TEAEs)

End point title	Percentage of Participants Who Experienced Treatment-emergent Adverse Events (TEAEs)

End point description:

TEAEs were defined as 1 or both of any AEs with an onset date on or after the study drug start date and no later than 30 days after permanent discontinuation of study drug or any AEs leading to premature discontinuation of study drug. Safety Analysis Set included all randomized participants who took at least 1 dose of study drug. Participants in the Safety Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

First dose date up to 3 days plus 30 days

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	36
Units: percentage of participants				
number (not applicable)	10.4	10.4	18.8	11.1

End point values	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	36	66	65	64
Units: percentage of participants				
number (not applicable)	2.8	9.1	16.9	9.4

End point values	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	29	30	20
Units: percentage of participants				
number (not applicable)	10.3	10.3	6.7	5.0

End point values	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: percentage of participants				
number (not applicable)	5.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Experienced Laboratory Abnormalities

End point title	Percentage of Participants Who Experienced Laboratory Abnormalities

End point description:

Treatment-emergent laboratory abnormalities were defined as values that increase at least 1 toxicity grade from the predose assessment associated with a treatment and occurring after the first dose of that treatment and on or before the date of the last dose of that treatment plus 30 days or before the first dose of the following treatment (if applicable), whichever occurs earlier. If the relevant predose laboratory value is missing, any abnormality of at least Grade 1 observed within the time frame specified above will be considered treatment emergent. Participants in the Safety Analysis Set with available data were analyzed.

End point type	Secondary

End point timeframe:

First dose date up to 3 days plus 30 days

End point values	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	96	96	96	36
Units: percentage of participants				
number (not applicable)				
Grade 1	19.8	17.7	14.6	13.9
Grade 2	3.1	3.1	3.1	2.8
Grade 3	5.2	3.1	1.0	5.6
Grade 4	0	0	0	0

End point values	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	36	66	66	66
Units: percentage of participants				
number (not applicable)				
Grade 1	19.4	19.7	20.0	20.3
Grade 2	2.8	1.5	7.7	3.1
Grade 3	5.6	3.0	3.1	1.6
Grade 4	0	0	0	0

End point values	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)	Cohort 4 H (F/TAF 200/25 mg adult tablet)	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	29	29	30	20
Units: percentage of participants				
number (not applicable)				
Grade 1	37.9	24.1	26.7	30.0
Grade 2	10.3	6.9	13.3	10.0
Grade 3	6.9	3.4	0	5.0
Grade 4	0	0	0	0

End point values	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)			
Subject group type	Subject analysis set			
Number of subjects analysed	20			
Units: percentage of participants				
number (not applicable)				
Grade 1	25.0			
Grade 2	5.0			
Grade 3	0			
Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Enrollment up to 58 days
Adverse events: First dose date up to 3 days plus 30 days

Adverse event reporting additional description:

All-cause mortality: All Randomized Analysis Set included all participants randomized into the study after screening.
Adverse events: Safety Analysis Set included all randomized participants who took at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)

Reporting group description:

Participants received treatment A (a single of B/F/TAF 50/200/25 mg adult tablet (1× 50/200/25 mg tablet) orally under fasted condition) on Days 1, 10, or 19 according to the treatment sequence for Cohort 1.

Reporting group title	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted condition) on Days 1, 10, or 19 according to the treatment sequence for Cohort 1.

Reporting group title	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)

Reporting group description:

Participants received treatment C (a single dose of F/TAF 200/25 mg pediatric tablet for oral suspension (4 × 50/6.25 mg tablet) orally under fasted condition) on Days 1, 10, or 19 according to the treatment sequence for Cohort 1.

Reporting group title	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)

Reporting group description:

Participants received treatment B (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fasted conditions) on Days 1 or 12 according to the treatment sequence for Cohort 2.

Reporting group title	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)

Reporting group description:

Participants received treatment D (a single dose of B/F/TAF 50/200/25 mg pediatric tablet for oral suspension (4 × 12.5/50/6.25 mg tablet) orally under fed conditions) on Days 1, or 12 according to the treatment sequence for Cohort 2.

Reporting group title	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)

Reporting group description:

Participants received treatment F (a single dose of B/F/TAF 15/60/7.5 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 3.

Reporting group title	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 3.

Reporting group title	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)

Reporting group description:

Participants received treatment G (a single dose of F/TAF 60/11 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 3.

Reporting group title	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)

Reporting group description:

Participants received treatment F (a single dose of F/TAF 60/10 mg pediatric tablet for oral suspension orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence under Cohort 4.

Reporting group title	Cohort 4 H (F/TAF 200/25 mg adult tablet)

Reporting group description:

Participants received treatment H (a single dose of F/TAF 200/25 mg adult tablet (1 × 200/25 mg tablet) orally under fasted conditions) on Days 1, 10, or 19 according to the treatment sequence for Cohort 4.

Reporting group title	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)

Reporting group description:

Participants received treatment I (a single dose of F/TAF 60/7.5 mg pediatric tablet for oral suspension (1 × 60/7.5 mg tablet) orally under fasted conditions) on Days 1, 10 , or 19 according to the treatment sequence for Cohort 4.

Reporting group title	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)

Reporting group description:

Participants received treatment J (a single dose of F/TAF (60/10 mg) pediatric tablet for oral suspension (1 × 60/10 mg tablet) orally under fasted conditions) on Days 1 or 13 according to the treatment sequence for Cohort 5.

Reporting group title	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)

Reporting group description:

Participants received treatment K (a single dose of F/TAF (60/10 mg) pediatric tablet for oral suspension (1 × 60/10 mg tablet) orally under fed conditions) on Days 1, or 13 according to the treatment sequence for Cohort 5.

Serious adverse events	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 96 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 66 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 65 (0.00%)	0 / 64 (0.00%)	1 / 29 (3.45%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 64 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 4 H (F/TAF 200/25 mg adult tablet)	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 29 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 29 (0.00%)	0 / 30 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Cohort 1 A (B/F/TAF 50/200/25 mg adult tablet)	Cohort 1 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 1 C (F/TAF 4 * 50/6.25 mg pediatric tablets)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 96 (3.13%)	4 / 96 (4.17%)	7 / 96 (7.29%)
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 96 (2.08%)	2 / 96 (2.08%)	3 / 96 (3.13%)
occurrences (all)	2	2	3
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 96 (3.13%)	3 / 96 (3.13%)	5 / 96 (5.21%)
occurrences (all)	3	3	5
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 96 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 96 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 96 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 2 B (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 2 D (B/F/TAF 4 * 12.5/50/6.25 mg pediatric tablets)	Cohort 3 E (B/F/TAF 15/60/7.5 mg pediatric tablet)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 36 (2.78%)	0 / 36 (0.00%)	3 / 66 (4.55%)
Nervous system disorders			
Headache			

subjects affected / exposed	1 / 36 (2.78%)	0 / 36 (0.00%)	3 / 66 (4.55%)
occurrences (all)	1	0	4
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 36 (2.78%)	0 / 36 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 36 (0.00%)	0 / 36 (0.00%)	0 / 66 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Cohort 3 F (F/TAF 60/10 mg pediatric tablet)	Cohort 3 G (F/TAF 60/11 mg pediatric tablet)	Cohort 4 F (F/TAF 60/10 mg pediatric tablet)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 65 (6.15%)	3 / 64 (4.69%)	2 / 29 (6.90%)
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 65 (3.08%)	2 / 64 (3.13%)	1 / 29 (3.45%)
occurrences (all)	2	2	1
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 65 (1.54%)	1 / 64 (1.56%)	1 / 29 (3.45%)
occurrences (all)	1	1	1
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 65 (1.54%)	0 / 64 (0.00%)	0 / 29 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 64 (0.00%)	0 / 29 (0.00%)
occurrences (all)	0	0	0

Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 65 (0.00%) 0	0 / 64 (0.00%) 0	0 / 29 (0.00%) 0

Non-serious adverse events	Cohort 4 H (F/TAF 200/25 mg adult tablet)	Cohort 4 I (F/TAF 60/7.5 mg pediatric tablet)	Cohort 5 J (F/TAF 60/10 mg pediatric tablet)
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 29 (3.45%)	2 / 30 (6.67%)	1 / 20 (5.00%)
Nervous system disorders Headache subjects affected / exposed occurrences (all)	1 / 29 (3.45%) 1	2 / 30 (6.67%) 2	0 / 20 (0.00%) 0
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0	0 / 30 (0.00%) 0	1 / 20 (5.00%) 1
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0 0 / 29 (0.00%) 0	0 / 30 (0.00%) 0 0 / 30 (0.00%) 0	1 / 20 (5.00%) 1 1 / 20 (5.00%) 1
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 29 (0.00%) 0	0 / 30 (0.00%) 0	0 / 20 (0.00%) 0

Non-serious adverse events	Cohort 5 K (F/TAF 60/10 mg pediatric tablet)		
Total subjects affected by non-serious adverse events subjects affected / exposed	1 / 20 (5.00%)		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Gastrointestinal disorders			

Nausea subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	 0 / 20 (0.00%) 0 0 / 20 (0.00%) 0		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 June 2020	- Addition of Cohort 3 to evaluate B/F/TAF and F/TAF fixed dose combination (FDC) pediatric tablets for oral suspension formulations containing alternative ratios of emtricitabine and tenofovir alafenamide - Updated to provide the description of formulations for alternative ratios of B/F/TAF and F/TAF FDC pediatric tablets for oral suspension
12 May 2021	- Addition of Cohort 4 to evaluate the relative bioavailability of F/TAF FDC pediatric tablet for oral suspension formulations relative to the adult F/TAF FDC tablet formulation - Addition of Cohort 5 to evaluate the effect of concomitant food intake on the PK of a F/TAF FDC pediatric tablet for oral suspension formulation

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported