ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
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Study Identification

Unique Protocol ID:	CNA109586
Brief Title:	KIVEXA Vs TRUVADA, Both Administered With Efavirenz, In ART-Naive Subjects (ASSERT)
Official Title:	Study of Once-Daily Abacavir/Lamivudine Versus Tenofovir/Emtricitabine, Administered With Efavirenz in Antiretroviral-Naive, HIV-1 Infected Adult Subjects
Secondary IDs:	

Study Status

Record Verification:	April 2011
Overall Status:	Completed
Study Start:	June 2007
Primary Completion:	December 2009 [Actual]
Study Completion:	December 2009 [Actual]

Sponsor/Collaborators

Sponsor:	GlaxoSmithKline
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No

Review Board:	Approval Status: Approved Approval Number: 2007/05/05 Board Name: SJH/AMNCH REC Board Affiliation: The Adelaide & Meath Hospital Dublin Phone: 0035314142000 Email: dan.lynch@amnch.ie
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Austria: Agency for Health and Food Safety Germany: Federal Institute for Drugs and Medical Devices Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment

Study Description

Brief Summary:	Recently, the fixed-dose combinations (FDC) KIVEXA™ (abacavir/lamivudine) and TRUVADA (tenofovir disoproxil fumarate/ emtricitabine) have facilitated the usage of once-daily regimens. However data from head-to-head randomized trials comparing these two FDCs as part of an initial regimen are not available at present. The long-term toxicity profiles of these regimens are of particular importance, as treatment of HIV is currently life-long and therefore, minimizing long-term toxicity and maximizing adherence and duration of regimen maintenance are critical therapy objectives. The primary endpoint is estimated glomerular filtration rate (GFR), as measured by the modified diet in renal disease (MDRD) equation, a validated estimate of renal function.
Detailed Description:	ViiV Healthcare is the new sponsor of this study, and GlaxoSmithKline is in the process of updating systems to reflect the change in sponsorship.

Conditions

Conditions:	Infection, Human Immunodeficiency Virus I HIV Infection
Keywords:	tenofovir HIV efavirenz naive lamivudine abacavir emtricitabine renal

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Safety Study
Enrollment:	392 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: ABC/3TC + EFV	Drug: Abacavir/lamivudine and efavirenz
Active Comparator: TDF/FTC + EFV	Drug: Tenofovir/Emtricitabine and efavirenz

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Subject is at least 18 years of age.
- Subject is antiretroviral-naïve (defined as having no previous therapy with any NNRTI and 14 days of prior therapy with any other antiretroviral).
- Subject has plasma HIV-1 RNA 1,000 copies/mL at screening. This test may be repeated once within the 45-day screening window.
- Subject is willing and able to understand and provide written informed consent prior to participation in this study.

- A female is eligible to enter and participate in the study if she is of:

    a. Non-childbearing potential (i.e., physiologically incapable of becoming pregnant, including any female who is post-menopausal); or,
    b. Child-bearing potential, has a negative pregnancy test at screen and agrees to one of the following methods of contraception (any contraception method must be used consistently and correctly, i.e., in accordance with both the approved product label and the instructions of a physician): Complete abstinence from intercourse from 2 weeks prior to administration of the investigational products, throughout the study, and for at least 2 weeks after discontinuation of all study medications Double barrier method (male condom/spermicide, male condom/diaphragm, diaphragm/spermicide). Hormonal contraception will not be considered adequate for inclusion into this study Any intrauterine device (IUD) with published data showing that the expected failure rate is <1% per year.

Sterilization (female subject or male partner of female subject).

- Prior to randomization, subjects must have been screened and be negative for the HLA-B*5701 allele. Test may be performed by local laboratory and results must be available for source document verification according to local practices.

Exclusion Criteria:

- Subject is in the initial acute phase of a CDC Clinical Category C infection at Baseline.
- Subject is enrolled in one or more investigational drug protocols, which may impact HIV RNA suppression.
- Subject is, in the opinion of the Investigator, unable to complete the study dosing period and protocol evaluations and assessments.
- Subject is either pregnant or breastfeeding.
- Subject suffers from a serious medical condition, which in the opinion of the Investigator would compromise the safety of the subject.
- Subject has a history of inflammatory bowel disease or other gastrointestinal dysfunction.
- Subject has any acute laboratory abnormality at screening.
- Subject has an estimated creatinine clearance within the screening period <50mL/min via the Cockcroft-Gault method.
- Alanine aminotransferase (ALT) >5 times the upper limit of normal.
- Subjects with a history of thyroid disease, hyperparathyroid disease, chronic hyper or hypocalcemia, vitamin D deficiency, or receiving thyroid hormone or parathyroid hormone replacement within 28 days prior to screening.
- Subjects with a history of systemic inflammatory arthritis.
- Subjects who are hepatitis B positive at screening.
- Subject requires treatment with radiation therapy or cytotoxic chemotherapeutic agents.
- Subject has received treatment with an HIV-1 immunotherapeutic vaccine or any agents with documented activity against HIV-1 in vitro within 28 days prior to Screening, or an anticipated need during the study.
- Subjects who require treatment with any of the following medications within 28 days of commencement of investigational product, or an anticipated need during the study:
- Medications with significant drug-drug interactions with efavirenz:voriconazole, terfenadine, astemizole, cisapride, ergot alkaloids (dihydroergotamine, ergonovine, ergotamine, methylergonovine), midazolam, triazolam, St. John’s wort, carbamazepine, phenytoin, phenobarbital, rifampin, pimozide, bepridil
- Medications which may impact on bone mineral density: oral or systemic corticosteroids, anticonvulsants, heparin, warfarin, cyclosporine, bisphosphonates, calcitonin, parathyroid hormone, Vitamin D supplements and analogues, Calcium supplements, oestrogen or progesterone replacement (oral hormonal contraception permitted), raloxifene, tamoxifen, testosterone or anabolic steroid replacement/supplements.
- Systemic interleukins or interferons

- Subject has a history of allergy to any of the protocol-specified medications or any excipients therein.
- Subject has evidence of genotypic resistance at screening (according to central lab interpretation) or prior documented evidence of genotypic and/or phenotypic (above threshold for reduced susceptibility) resistance to any of the following drugs: efavirenz, abacavir, lamivudine, tenofovir, emtricitabine.
- Subjects who are unsuitable for DEXA scanning should be excluded, including 1) Less than three vertebra in the range of L1 to L4 that are suitable for BMD measurement by DEXA, or 2) Bilateral hip replacement.
- The subject has previously participated in an experimental drug and/or vaccine trial(s) within 60 days or 5 half-lives, or twice the duration of the biological effect of the experimental drug or vaccine - whichever is longer, prior to screening for the study.
- The subject will participate simultaneously in another clinical study.

Contacts/Locations

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References

Citations: Post FA, Moyle GJ, Stellbrink HJ, et al. Randomized comparison of renal effects, efficacy, and safety with once-daily abacavir/lamivudine versus tenofovir/emtricitabine, administered with efavirenz, in antiretroviral-naive, HIV-1-infected adults: 48-week results from the ASSERT study. [JAIDS]. 2010;55(1):49-57.

Post F, Moyle G, Stellbrink H-J, et al. Once daily abacavir/lamivudine versus tenofovir/emtricitabine, administered with efavirenz, in antiretroviral-naïve, HIV-1 infected adults - 48-week results from the prospective, randomized ASSERT Study. J Acquir Immune Defic Syndr 2010, [Epub ahead of print]; 10.1097/QAI.0b013e3181dd911e

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD

	Description
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Overall Study

	ABC/3TC FDC	TDF/FTC FDC
Started	195 [1]	197 [2]
Completed	115	134
Not Completed	80	63
Adverse Event	28	26
Insufficient Viral Load Response	4	2
Protocol-defined Virological Failure	7	0
Non-compliance	2	4
Lost to Follow-up	7	8
Treatment Eligibility Criteria Not Met	3	0
Protocol Violation	7	2
Investigator Decision	4	3
Withdrawal by Subject	7	7
Disease Progression	1	0
Participant Moved	2	0
Participant not able to perform Week 96	1	0
Participant moved.Week 96 visit, no scan	1	0
Prohibited Medication	1	2
Participant planning pregnancy	1	0
Participant overweight, no scan possible	1	0
No scan facilities	0	2
Pregnancy	0	3
Not Exposed to Study Drug	3	4

[1] Three participants were randomized but were not exposed to study drug (ABC/3TC).
[2] Four participants were randomized but were not exposed to study drug (TDF/FTC).

Baseline Characteristics

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Baseline Measures

	ABC/3TC FDC	TDF/FTC FDC	Total
Number of Participants	192	193	385
Age, Continuous [1] [units: Years] Median (Full Range)	38.0 (19 to 70)	36.0 (18 to 66)	37.0 (18 to 70)
Gender, Male/Female [1] [units: Participants]			
Female	33	40	73
Male	159	153	312
Race/Ethnicity, Customized [1] [units: participants]			
African American/African Heritage	26	30	56
American Indian or Alaska Native	11	7	18
Asian	2	5	7
White	153	151	304

[1] The Intent-to-Treat (ITT)-Exposed (E) Population, comprised of all randomized participants who received at least one dose of study medication, was used for all baseline characteristics.

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 48
Measure Description	Change from baseline was calculated as the Week 48 value minus the baseline value. GFR is a measure of the rate at which blood is filtered by the kidney. MDRD is an equation (calculation) used to estimate GFR in participants with impaired renal function based on serum creatinine, age, race, and gender. GFR (mL/min/1.73 m^2) = 175 * (Scr)^-1.154 * (Age)^-0.203 * (0.742 if female) * (1.212 if African American) (conventional units). mL, milliliters; min, minute; m^2, meters squared; Scr, serum creatinine; BMI, body mass index.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

Intent-to-Treat-Exposed (ITT-E) Population: all randomized participants who received at least one dose of study medication

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 48 [units: milliliters per minute (mL/min)/1.73 m^2] Mean (Standard Error)	0.22 (0.890)	1.18 (0.828)

Statistical Analysis 1 for Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 48

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.435
	Comments	The model includes the following covariates: treatment, visit, baseline GFR by MDRD, baseline BMI, race group, treatment*visit, baseline GFR by MDRD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 24
Measure Description	Change from baseline was calculated as the Week 24 value minus the baseline value. GFR is a measure of the rate at which blood is filtered by the kidney. MDRD is an equation (calculation) used to estimate GFR in participants with impaired renal function based on serum creatinine, age, race, and gender. GFR (mL/min/1.73 m^2) = 175 * (Scr)^-1.154 * (Age)^-0.203 * (0.742 if female) * (1.212 if African American) (conventional units). mL, milliliters; min, minute; m^2, meters squared; Scr, serum creatinine.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description
ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193

	ABC/3TC FDC	TDF/FTC FDC
Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 24 [units: mL/min/1.73m^2] Mean (Standard Error)	2.78 (0.884)	0.43 (0.842)

Statistical Analysis 1 for Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 24

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.057
	Comments	The model includes the following covariates: treatment, visit, baseline GFR by MDRD, baseline BMI, race group, age group, treatment*visit, baseline GFR by MDRD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

3. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 96
Measure Description	Change from baseline was calculated as the Week 96 value minus the baseline value. GFR is a measure of the rate at which blood is filtered by the kidney. MDRD is an equation (calculation) used to estimate GFR in participants with impaired renal function based on serum creatinine, age, race, and gender. GFR (mL/min/1.73 m^2) = 175 * (Scr)^-1.154 * (Age)^-0.203 * (0.742 if female) * (1.212 if African American) (conventional units). mL, milliliters; min, minute; m^s, meters squared; Scr, serum creatinine.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 96 [units: mL/min/1.73m^2] Mean (Standard Error)	1.48 (1.022)	-1.15 (0.944)

Statistical Analysis 1 for Mean Change From Baseline in Estimated Glomerular Filtration Rate (GFR), Calculated by Modification of Diet in Renal Disease (MDRD) Equation, at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.060
	Comments	The model includes the following covariates: treatment, visit, baseline GFR by MDRD, baseline BMI, race group, treatment*visit, baseline GFR by MDRD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 24

Measure Description	Change from baseline was calculated as the Week 24 value minus the baseline value. Cockcroft-Gault is an equation (calculation) used to estimate GFR based on serum creatinine, weight, and gender. GFR = (140 - age) * (mass in kg) * (0.85 if female) divided by 72 * serum creatinine in mg/dL. mg, milligram; dL, deciliter; kg, kilogram; CG, Cockcroft-Gault.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description
ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 24 [units: mL/min] Mean (Standard Error)	4.27 (0.944)	2.54 (0.897)

Statistical Analysis 1 for Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 24

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.186
	Comments	The model includes the following covariates: treatment, visit, baseline GFR by CG, baseline BMI, race group, age group, hypertension, treatment*visit, baseline GFR by CG*visit and baseline BMI*visit.

	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 48
Measure Description	Change from baseline was calculated as the Week 48 value minus the baseline value. Cockcroft-Gault is an equation (calculation) used to estimate GFR based on serum creatinine, weight, and gender. GFR = (140 - age) * (mass in kg) * (0.85 if female) divided by 72 * serum creatinine in mg/dL. mg, milligram; dL, deciliter; kg, kilogram.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description
ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 48 [units: mL/min] Mean (Standard Error)	2.66 (1.005)	3.80 (0.933)

Statistical Analysis 1 for Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 48

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.413
	Comments	The model includes the following covariates: treatment, visit, baseline GFR by CG, baseline BMI, race group, age group, hypertension, treatment*visit, baseline GFR by CG*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

6. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 96
Measure Description	Change from baseline was calculated as the Week 96 value minus the baseline value. Cockcroft-Gault is an equation (calculation) used to estimate GFR based on serum creatinine, weight, and gender. GFR = (140 - age) * (mass in kg) * (0.85 if female) divided by 72 * serum creatinine in mg/dL. mg, milligram; dL, deciliter; kg, kilogram.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 96 [units: mL/min] Mean (Standard Error)	4.37 (1.228)	2.68 (1.133)

Statistical Analysis 1 for Mean Change From Baseline in Estimated GFR, Calculated by Cockcroft-Gault Equation, at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.315
	Comments	The model includes the following covariates: treatment, visit, baseline GFR by CG, baseline BMI, race group, baseline CD4, treatment*visit, baseline GFR by CG*visit, baseline BMI*visit and baseline CD4*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

7. Secondary Outcome Measure:

Measure Title	Number of Participants With Decline From Baseline in Estimated GFR, Calculated by MDRD and Cockcroft-Gault Equations, of >=10 mL/Min/1.73 m^2 (mL/Min for Cockcroft-Gault), >=20 mL/Min/1.72 m^2, >=10%, and >=20% at Week 24
Measure Description	mL, milliliter; min, minute; m^2, meters squared
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn from the study by Week 24.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	156	173

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants With Decline From Baseline in Estimated GFR, Calculated by MDRD and Cockcroft-Gault Equations, of >=10 mL/Min/1.73 m^2 (mL/Min for Cockcroft-Gault), >=20 mL/Min/1.72 m^2, >=10%, and >=20% at Week 24 [units: participants]		
>=10 mL/min, MDRD	16	26
>=10 mL/min, Cockcroft-Gault	16	20
>=20 mL/min, MDRD	4	6
>=20 mL/min, Cockcroft-Gault	3	4
>=10%, MDRD	15	24
>=10%, Cockcroft-Gault	10	17
>=20%, MDRD	2	3
>=20%, Cockcroft-Gault	2	3

8. Secondary Outcome Measure:

Measure Title	Number of Participants With Decline From Baseline in Estimated GFR, Calculated by MDRD and Cockcroft-Gault Equations, of >=10 mL/Min/1.73m^2 (mL/Min for Cockcroft-Gault), >=20 mL/Min/1.72m^2, >=10%, and >=20% at Week 48
Measure Description	mL, milliliter; min, minute; m^2, meters squared
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 48.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	136	159
Number of Participants With Decline From Baseline in Estimated GFR, Calculated by MDRD and Cockcroft-Gault Equations, of >=10 mL/Min/1.73m^2 (mL/Min for Cockcroft-Gault), >=20 mL/Min/1.72m^2, >=10%, and >=20% at Week 48 [units: participants]		
>=10 mL/min, MDRD	23	21
>=10 mL/min, Cockcroft-Gault	15	14
>=20 mL/min, MDRD	4	3
>=20 mL/min, Cockcroft-Gault	4	2
>=10%, MDRD	21	21
>=10%, Cockcroft-Gault	11	9
>=20%, MDRD	4	2
>=20%, Cockcroft-Gault	3	0

9. Secondary Outcome Measure:

Measure Title	Number of Participants With Decline From Baseline in Estimated GFR, Calculated by MDRD and Cockcroft-Gault Equations, of >=10 mL/Min/1.73m^2 (mL/Min for Cockcroft-Gault), >=20 mL/Min/1.72m^2, >=10%, and >=20% at Week 96
Measure Description	mL, milliliter; min, minute; m^2, meters squared
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD

	Description
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	111	131
Number of Participants With Decline From Baseline in Estimated GFR, Calculated by MDRD and Cockcroft-Gault Equations, of >=10 mL/Min/1.73m^2 (mL/Min for Cockcroft-Gault), >=20 mL/Min/1.72m^2, >=10%, and >=20% at Week 96 [units: participants]		
>=10 mL/min, MDRD	15	38
>=10 mL/min, Cockcroft-Gault	11	19
>=20 mL/min, MDRD	4	7
>=20 mL/min, Cockcroft-Gault	4	5
>=10%, MDRD	15	27
>=10%, Cockcroft-Gault	12	16
>=20%, MDRD	3	6
>=20%, Cockcroft-Gault	3	4

10. Secondary Outcome Measure:

Measure Title	Number of Participants With National Kidney Foundation Chronic Kidney Disease Stage 1, 2, 3, 4, or 5 Categories of Renal Function at Week 24
Measure Description	Normal: GFR >=60 mL/min/1.73 m^2 and creatinine ratio <=200 mg/g GFR; Stage 1: GFR >=90 mL/min/1.73 m^2 and creatinine ratio >200 mg/g; Stage 2: GFR >=60-<90 mL/min/1.73 m^2 and creatinine ratio >200 mg/g; Stage 3: GFR >=30-<60 mL/min/1.73 m^2; Stage 4: GFR >=15-<30 mL/min/1.73 m^2; Stage 5: GFR <15 mL/min/1.73 m^2. mL, milliliter; min, minute; m^2, meters squared; mg, milligram; g, gram.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 24.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	114	135
Number of Participants With National Kidney Foundation Chronic Kidney Disease Stage 1, 2, 3, 4, or 5 Categories of Renal Function at Week 24 [units: participants]		
Normal	97	114
Stage 1	11	15
Stage 2	5	5
Stage 3	1	1
Stage 4	0	0
Stage 5	0	0

11. Secondary Outcome Measure:

Measure Title	Number of Participants With National Kidney Foundation Chronic Kidney Disease Stage 1, 2, 3, 4, or 5 Categories of Renal Function at Week 48
Measure Description	Normal: GFR >=60 mL/min/1.73 m^2 and creatinine ratio <=200 mg/g GFR; Stage 1: GFR >=90 mL/min/1.73 m^2 and creatinine ratio >200 mg/g; Stage 2: GFR >=60-<90 mL/min/1.73 m^2 and creatinine ratio >200 mg/g; Stage 3: GFR >=30-<60 mL/min/1.73 m^2; Stage 4: GFR >=15-<30 mL/min/1.73 m^2; Stage 5: GFR <15 mL/min/1.73 m^2. mL, milliliter; min, minute; m^2, meters squared; mg, milligram; g, gram.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 48.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	112	133
Number of Participants With National Kidney Foundation Chronic Kidney Disease Stage 1, 2, 3, 4, or 5 Categories of Renal Function at Week 48 [units: participants]		
Missing	12	19
Normal	90	106
Stage 1	7	5
Stage 2	3	3
Stage 3	0	0
Stage 4	0	0
Stage 5	0	0

12. Secondary Outcome Measure:

Measure Title	Number of Participants With National Kidney Foundation Chronic Kidney Disease Stage 1, 2, 3, 4, or 5 Categories of Renal Function at Week 96
Measure Description	Normal: GFR >=60 mL/min/1.73 m^2 and creatinine ratio <=200 mg/g GFR; Stage 1: GFR >=90 mL/min/1.73 m^2 and creatinine ratio >200 mg/g; Stage 2: GFR >=60-<90 mL/min/1.73 m^2 and creatinine ratio >200 mg/g; Stage 3: GFR >=30-<60 mL/min/1.73 m^2; Stage 4: GFR >=15-<30 mL/min/1.73 m^2; Stage 5: GFR <15 mL/min/1.73 m^2. mL, milliliter; min, minute; m^2, meters squared; mg, milligram; g, gram.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	93	109
Number of Participants With National Kidney Foundation Chronic Kidney Disease Stage 1, 2, 3, 4, or 5 Categories of Renal Function at Week 96 [units: participants]		
Missing	11	18
Normal	75	83
Stage 1	3	4
Stage 2	4	4
Stage 3	0	0
Stage 4	0	0
Stage 5	0	0

13. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 24
Measure Description	BMD is a measure (grams [g] per centimeters cubed [cm^3]) of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones. The standard error (SE) of both treatment groups was based on the model on the log scale.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description
ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 24 [units: percent change] Mean (Standard Error)	-2.12 (0.0011)	-3.30 (0.0011)

Statistical Analysis 1 for Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 24

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	The model includes the following covariates: treatment, visit, baseline spine BMD, baseline BMI, race group, age group, hypertension, treatment*visit, baseline spine BMD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

14. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 24
Measure Description	BMD is a measure (grams per cm^3) of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones. The standard error (SE) of both treatment groups was based on the model on the log scale.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 24 [units: percent change] Mean (Standard Error)	-1.19 (0.0007)	-2.73 (0.0007)

Statistical Analysis 1 for Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 24

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	The model includes the following covariates: treatment, visit, baseline hip BMD, baseline BMI, race group, risk factor, country group, treatment*visit, baseline hip BMD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

15. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 48
Measure Description	BMD is a measure (grams per cm^3) of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones. The standard error (SE) of both treatment groups was based on the model on the log scale.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 48 [units: percent change] Mean (Standard Error)	-1.59 (0.0013)	-2.41 (0.0012)

Statistical Analysis 1 for Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 48

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.036
	Comments	The model includes the following covariates: treatment, visit, baseline spine BMD, baseline BMI, race group, age group, treatment*visit, baseline spine BMD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

16. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 48
Measure Description	BMD is a measure (grams per cm^3) of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones. The standard error (SE) of both treatment groups was based on the model on the log scale.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 48 [units: percent change] Mean (Standard Error)	-1.90 (0.0010)	-3.56 (0.0009)

Statistical Analysis 1 for Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 48

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	The model includes the following covariates: treatment, visit, baseline hip BMD, baseline BMI, race group, risk factor, prohibited medication, previous fracture, treatment*visit, baseline hip BMD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	Correlation matrix for within-subject errors is unstructured.

17. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 96
Measure Description	BMD is a measure (grams per cm^3) of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones. The standard error (SE) of both treatment groups was based on the model on the log scale.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 96 [units: percent change] Mean (Standard Error)	-0.87 (0.0017)	-1.70 (0.0015)

Statistical Analysis 1 for Percent Change From Baseline in Lumbar Spine Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.112
	Comments	The model includes the following covariates: treatment, visit, baseline spine BMD, baseline BMI, race group, age group, treatment*visit, baseline spine BMD*visit and baseline BMI*visit.
	Method	Mixed Models Analysis
	Comments	correlation matrix for within-subject errors is unstructured.

18. Secondary Outcome Measure:

Measure Title	Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 96

Measure Description	BMD is a measure (grams per cm^3) of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones. The standard error (SE) of both treatment groups was based on the model on the log scale.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 96 [units: percent change] Mean (Standard Error)	-2.17 (0.0013)	-3.55 (0.0012)

Statistical Analysis 1 for Percent Change From Baseline in Hip Bone Mineral Density (BMD), Measured by Dual-energy X-ray Absorptiometry (DXA), at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.001
	Comments	The model includes the following covariates: treatment, visit, baseline hip BMD, baseline BMI, race group, risk factor, prohibited medication, previous fracture, treatment*visit, baseline hip BMD*visit, and baseline BMI*visit.

	Method	Mixed Models Analysis
	Comments	The correlation matrix for within-subject errors is unstructured.

19. Secondary Outcome Measure:

Measure Title	Number of Participants With a Decline From Baseline in Lumbar Spine and Hip Bone Mineral Density (BMD) >=2.0% and >=6.0% at Week 24
Measure Description	BMD is a measure of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 24/did not have a DXA scan performed. DXA, dual energy x-ray absorptiometry.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	142	165
Number of Participants With a Decline From Baseline in Lumbar Spine and Hip Bone Mineral Density (BMD) >=2.0% and >=6.0% at Week 24 [units: participants]		
>=2%, spine, n=142, 165	73	115
>=6%, spine, n=142, 165	10	17
>=2%, hip, n=137, 160	38	93
>=6%, hip, n=137, 160	1	6

20. Secondary Outcome Measure:

Measure Title	Number of Participants With a Decline From Baseline in Lumbar Spine and Hip Bone Mineral Density (BMD) >=2.0% and >=6.0% at Week 48
Measure Description	BMD is a measure of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 48/did not have a DXA scan performed. DXA, dual energy x-ray absorptiometry.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	125	141
Number of Participants With a Decline From Baseline in Lumbar Spine and Hip Bone Mineral Density (BMD) >=2.0% and >=6.0% at Week 48 [units: participants]		
>=2%, spine, n=125, 141	51	84
>=6%, spine, n=125, 141	5	13
>=2%, hip, n=119, 140	54	111
>=6%, hip, n=119, 140	3	17

21. Secondary Outcome Measure:

Measure Title	Number of Participants With a Decline From Baseline in Lumbar Spine and Hip Bone Mineral Density (BMD) >=2.0% and >=6.0% at Week 96

Measure Description	BMD is a measure of the mineral content of bone in a particular skeletal area. DXA scans use low energy x-rays to measure the density of bones.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 96/did not have a DXA scan performed. DXA, dual energy x-ray absorptiometry.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	59	79
Number of Participants With a Decline From Baseline in Lumbar Spine and Hip Bone Mineral Density (BMD) >=2.0% and >=6.0% at Week 96 [units: participants]		
>=2%, spine, n=59, 79	21	39
>=6%, spine, n=59, 79	3	8
>=2%, hip, n=58, 76	33	52
>=6%, hip, n=58, 76	1	13

22. Secondary Outcome Measure:

Measure Title	Number of Participants Meeting World Health Organization (WHO) Criteria for Osteopenia (T-score of -2.5 to -1.0) and Osteoporosis (T-score of <-2.5) at Week 24
Measure Description	The T-score is a radiographic diagnosis that compares bone mineral density (BMD) to that of a "normal, healthy, 30-year-old female". The lower the T-score, the lower the BMD. A T-score of +1 to -1 is normal. A T-score decrease of -1 indicates a 10%-15% decrease in BMD.
Time Frame	Week 24

Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 24.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	149	173
Number of Participants Meeting World Health Organization (WHO) Criteria for Osteopenia (T-score of -2.5 to -1.0) and Osteoporosis (T-score of <-2.5) at Week 24 [units: participants]		
Osteopenia, spine, n=147, 173	41	68
Osteporosis, spine, n=147, 173	16	9
Osteopenia, hip, n=149, 170	38	54
Osteoporosis, hip, n=149, 170	4	1

23. Secondary Outcome Measure:

Measure Title	Number of Participants Meeting World Health Organization (WHO) Criteria for Osteopenia (T-score of -2.5 to -1.0) and Osteoporosis (T-score of <-2.5) at Week 48
Measure Description	The T-score is a radiographic diagnosis that compares bone mineral density (BMD) to that of a "normal, healthy, 30-year-old female". The lower the T-score, the lower the BMD. A T-score of +1 to -1 is normal. A T-score decrease of -1 indicates a 10%-15% decrease in BMD.
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 48.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	132	147
Number of Participants Meeting World Health Organization (WHO) Criteria for Osteopenia (T-score of -2.5 to -1.0) and Osteoporosis (T-score of <-2.5) at Week 48 [units: participants]		
Osteopenia, spine, n=132, 147	41	57
Osteporosis, spine, n=132, 147	15	5
Osteopenia, hip, n=130, 147	37	50
Osteoporosis, hip, n=130, 147	4	0

24. Secondary Outcome Measure:

Measure Title	Number of Participants Meeting World Health Organization (WHO) Criteria for Osteopenia (T-score of -2.5 to -1.0) and Osteoporosis (T-score of <-2.5) at Week 96
Measure Description	The T-score is a radiographic diagnosis that compares bone mineral density (BMD) to that of a "normal, healthy, 30-year-old female". The lower the T-score, the lower the BMD. A T-score of +1 to -1 is normal. A T-score decrease of -1 indicates a 10%-15% decrease in BMD.
Time Frame	Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	65	82
Number of Participants Meeting World Health Organization (WHO) Criteria for Osteopenia (T-score of -2.5 to -1.0) and Osteoporosis (T-score of <-2.5) at Week 96 [units: participants]		
Osteopenia, spine, n=64, 82	21	34
Osteporosis, spine, n=64, 82	5	3
Osteopenia, hip, n=65, 80	20	31
Osteoporosis, hip, n=65, 80	0	0

25. Secondary Outcome Measure:

Measure Title	Number of Participants Experiencing an Adverse Event (AE) Leading to Discontinuation by Week 24
Measure Description	An adverse event was any untoward medical occurrence in a participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Adverse events occurring in two or more participants are presented.
Time Frame	Baseline to Week 24
Safety Issue?	No

Analysis Population Description

Safety Population: all randomized participants who received at least one dose of study medication

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants Experiencing an Adverse Event (AE) Leading to Discontinuation by Week 24 [units: participants]		
Any event	26	14
Drug hypersensitivity	11	1
Rash	2	3
Dizziness	0	2
Hypersensitivity	3	0
Drug eruption	1	1

26. Secondary Outcome Measure:

Measure Title	Number of Participants Experiencing an Adverse Event (AE) Leading to Discontinuation by Week 48
Measure Description	An adverse event was any untoward medical occurrence in a participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Adverse events occurring in two or more participants are presented.
Time Frame	Baseline to Week 48
Safety Issue?	No

Analysis Population Description

Safety Population: all randomized participants who received at least one dose of study medication

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants Experiencing an Adverse Event (AE) Leading to Discontinuation by Week 48 [units: participants]		
Any event	29	21
Drug hypersensitivity	11	1
Bone density decreased	0	2
Rash	2	3
Dizziness	1	3
Hypersensitivity	3	0
Drug eruption	1	1

27. Secondary Outcome Measure:

Measure Title	Number of Participants Experiencing an Adverse Event (AE) Leading to Discontinuation by Week 96
Measure Description	An adverse event was any untoward medical occurrence in a participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Adverse events occurring in two or more participants are presented.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

Safety Population: all randomized participants who received at least one dose of study medication

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants Experiencing an Adverse Event (AE) Leading to Discontinuation by Week 96 [units: participants]		
Any event	33	28
Drug hypersensitivity	11	1
Bone density decreased	0	8
Rash	2	3
Dizziness	1	3
Hypersensitivity	3	0
Abnormal dreams	3	0
Drug eruption	1	1
Depression	0	2

28. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Total Cholesterol at Week 24
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <200 mg/dL, desirable; 200-<240 mg/dL, borderline high; >=240 mg/dL, high. mg, milligram; dL, deciliter.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Total Cholesterol at Week 24 [units: participants]		
Desirable to desirable	54	104
Desirable to borderline high	47	29
Desirable to high	32	9
Borderline high to desirable	1	3
Borderline high to borderline high	2	9
Borderline high to high	10	6
High to desirable	0	0
High to borderline high	0	0
High to high	3	2

29. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Total Cholesterol at Week 48
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <200 mg/dL, desirable; 200-<240 mg/dL, borderline high; >=240 mg/dL, high. mg, milligram; dL, deciliter.

Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Total Cholesterol at Week 48 [units: participants]		
Desirable to desirable	46	96
Desirable to borderline high	52	37
Desirable to high	36	9
Borderline high to desirable	1	1
Borderline high to borderline high	2	9
Borderline high to high	10	8
High to desirable	0	0
High to borderline high	0	0
High to high	3	2

30. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Total Cholesterol at Week 96
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <200 mg/dL, desirable; 200-<240 mg/dL, borderline high; >=240 mg/dL, high. mg, milligram; dL, deciliter.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Total Cholesterol at Week 96 [units: participants]		
Desirable to desirable	39	86
Desirable to borderline high	49	47
Desirable to high	46	10
Borderline high to desirable	1	1
Borderline high to borderline high	2	9
Borderline high to high	10	8
High to desirable	0	0
High to borderline high	0	0

	ABC/3TC FDC	TDF/FTC FDC
High to high	3	2

31. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Low-density Lipoprotein (LDL) at Week 24
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <100 mg/dL, optimal; 100-<130 mg/dL, near/above optimal; 130-<160 mg/dL, borderline high; 160-<190 mg/dL, high; >=190 mg/dL, very high.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Low-density Lipoprotein (LDL) at Week 24 [units: participants]		
Optimal to optimal	22	46
Optimal to near or above optimal	41	43
Optimal to borderline high	22	11
Optimal to high	6	1

	ABC/3TC FDC	TDF/FTC FDC
Optimal to very high	1	0
Near or above optimal to optimal	0	5
Near or above optimal to near or above optimal	6	22
Near or above optimal to borderline high	17	11
Near or above optimal to high	12	5
Near or above optimal to very high	4	1
Borderline high to optimal	0	0
Borderline high to near or above optimal	1	6
Borderline high to borderline high	2	3
Borderline high to high	4	3
Borderline high to very high	3	2
High to optimal	0	0
High to near or above optimal	0	0
High to borderline high	0	0
High to high	1	1
High to very high	0	0
Very high to optimal	0	0
Very high to near or above optimal	0	0
Very high to borderline high	1	0
Very high to high	0	0
Very high to very high	1	1

32. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Low-density Lipoprotein (LDL) at Week 48

Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <100 mg/dL, optimal; 100-<130 mg/dL, near/above optimal; 130-<160 mg/dL, borderline high; 160-<190 mg/dL, high; >=190 mg/dL, very high.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Low-density Lipoprotein (LDL) at Week 48 [units: participants]		
Optimal to optimal	20	42
Optimal to near or above optimal	38	46
Optimal to borderline high	27	12
Optimal to high	8	1
Optimal to very high	1	0
Near or above optimal to optimal	0	3
Near or above optimal to near or above optimal	4	21
Near or above optimal to borderline high	19	13
Near or above optimal to high	12	6
Near or above optimal to very high	4	1
Borderline high to optimal	0	0

	ABC/3TC FDC	TDF/FTC FDC
Borderline high to near or above optimal	1	3
Borderline high to borderline high	2	5
Borderline high to high	3	4
Borderline high to very high	4	2
High to optimal	0	0
High to near or above optimal	0	0
High to borderline high	0	0
High to high	1	1
High to very high	0	0
Very high to optimal	0	0
Very high to near or above optimal	0	0
Very high to borderline high	1	0
Very high to high	0	0
Very high to very high	1	1

33. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Low-density Lipoprotein (LDL) at Week 96
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <100 mg/dL, optimal; 100-<130 mg/dL, near/above optimal; 130-<160 mg/dL, borderline high; 160-<190 mg/dL, high; >=190 mg/dL, very high.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Low-density Lipoprotein (LDL) at Week 96 [units: participants]		
Optimal to optimal	18	37
Optimal to near or above optimal	35	46
Optimal to borderline high	29	17
Optimal to high	9	1
Optimal to very high	3	0
Near or above optimal to optimal	0	1
Near or above optimal to near or above optimal	4	19
Near or above optimal to borderline high	17	16
Near or above optimal to high	12	7
Near or above optimal to very high	6	2
Borderline high to optimal	0	0
Borderline high to near or above optimal	1	3
Borderline high to borderline high	2	5
Borderline high to high	3	3
Borderline high to very high	4	3
High to optimal	0	0
High to near or above optimal	0	0

	ABC/3TC FDC	TDF/FTC FDC
High to borderline high	0	0
High to high	1	1
High to very high	0	0
Very high to optimal	0	0
Very high to near or above optimal	0	0
Very high to borderline high	1	0
Very high to high	0	0
Very high to very high	1	1

34. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting High-density Lipoprotein (HDL) at Week 24
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <40 mg/dL, low; 40-<60 mg/dL, normal; >=60 mg/dL, high.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting High-density Lipoprotein (HDL) at Week 24 [units: participants]		
Low to low	19	36
Low to normal	72	66
Low to high	10	9
Normal to low	0	1
Normal to normal	12	30
Normal to high	26	12
High to low	0	0
High to normal	0	3
High to high	10	5

35. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting High-density Lipoprotein (HDL) at Week 48
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <40 mg/dL, low; 40-<60 mg/dL, normal; >=60 mg/dL, high.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting High-density Lipoprotein (HDL) at Week 48 [units: participants]		
Low to low	17	28
Low to normal	67	73
Low to high	18	10
Normal to low	0	0
Normal to normal	11	23
Normal to high	27	20
High to low	0	0
High to normal	0	3
High to high	10	5

36. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting High-density Lipoprotein (HDL) at Week 96
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <40 mg/dL, low; 40-<60 mg/dL, normal; >=60 mg/dL, high.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting High-density Lipoprotein (HDL) at Week 96 [units: participants]		
Low to low	11	23
Low to normal	66	75
Low to high	25	13
Normal to low	0	0
Normal to normal	8	17
Normal to high	30	27
High to low	0	0
High to normal	0	1
High to high	10	7

37. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Triglycerides at Week 24
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <150 mg/dL, normal; 150-<200 mg/dL, borderline high; 200-<500 mg/dL, high; >=500 mg/dL, very high.
Time Frame	Baseline, Week 24

Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Triglycerides at Week 24 [units: participants]		
Normal to normal	63	78
Normal to borderline high	21	19
Normal to high	23	9
Normal to very high	0	0
Borderline high to normal	5	7
Borderline high to borderline high	5	10
Borderline high to high	9	15
Borderline high to very high	0	0
High to normal	2	6
High to borderline high	5	3
High to high	12	15
High to very high	3	0
Very high to normal	0	0
Very high to borderline high	0	0

	ABC/3TC FDC	TDF/FTC FDC
Very high to high	0	1
Very high to very high	1	0

38. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Triglycerides at Week 48
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <150 mg/dL, normal; 150-<200 mg/dL, borderline high; 200-<500 mg/dL, high; >=500 mg/dL, very high.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Triglycerides at Week 48 [units: participants]		
Normal to normal	55	70
Normal to borderline high	22	23
Normal to high	30	12

	ABC/3TC FDC	TDF/FTC FDC
Normal to very high	0	1
Borderline high to normal	4	6
Borderline high to borderline high	5	7
Borderline high to high	11	19
Borderline high to very high	0	0
High to normal	2	5
High to borderline high	4	3
High to high	12	15
High to very high	4	0
Very high to normal	0	0
Very high to borderline high	0	0
Very high to high	0	1
Very high to very high	1	0

39. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Triglycerides at Week 96
Measure Description	Blood samples were collected from participants for analysis of their lipid profile. Data are categorized by the maximum post-baseline threshold reached. <150 mg/dL, normal; 150->200 mg/dL, borderline high; 200-<500 mg/dL, high;>= 500 mg/dL, very high.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD

	Description
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Change From Baseline in National Cholesterol Education Program (NCEP) Thresholds for Fasting Triglycerides at Week 96 [units: participants]		
Normal to normal	47	55
Normal to borderline high	25	31
Normal to high	34	20
Normal to very high	1	1
Borderline high to normal	4	5
Borderline high to borderline high	4	8
Borderline high to high	11	19
Borderline high to very high	1	0
High to normal	2	5
High to borderline high	4	2
High to high	11	16
High to very high	5	0
Very high to normal	0	0
Very high to borderline high	0	0
Very high to high	0	1
Very high to very high	1	0

40. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Treatment-emergent Division of AIDS (DAIDS) Toxicities at Week 24

Measure Description	The DAIDS toxicity table provides descriptive terminology for grading the severity of adult adverse events. Laboratory grades also provide ranges for each parameter. Grade 1: mild, Grade 2: moderate, Grade 3: severe, Grade 4: potentially life-threatening. LDL, low-density lipid; HDL, high-density lipid. Treatment emergent refers to any toxicity that was not present prior to the start of study drug treatment.
Time Frame	Week 24
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Treatment-emergent Division of AIDS (DAIDS) Toxicities at Week 24 [units: participants]		
Cholesterol, Grade 3	6	1
Cholesterol, Grade 4	0	0
LDL cholesterol, Grade 3	8	3
LDL cholesterol, Grade 4	0	0
Non-HDL cholesterol, Grade 3	19	5
Non-HDL cholesterol, Grade 4	0	0
Triglycerides, Grade 3	2	0
Triglycerides, Grade 4	0	0
Alanine aminotransferase, Grade 3	1	3
Alanine aminotransferase, Grade 4	1	1
Aspartate aminotransferase, Grade 3	1	0

	ABC/3TC FDC	TDF/FTC FDC
Aspartate aminotransferase, Grade 4	1	2
Alkaline phosphatase, Grade 3	0	1
Alkaline phosphatase, Grade 4	0	0
Creatinine kinase, Grade 3	0	1
Creatinine kinase, Grade 4	1	1
Phosphorus inorganic, Grade 3	1	1
Phosphorus inorganic, Grade 4	0	0
Lipase, Grade 3	3	1
Lipase, Grade 4	2	0
Hyperkalaemia, Grade 3	0	0
Hyperkalaemia, Grade 4	1	1
Glomerular filtration rate, MDRD, Grade 3	1	1
Glomerular filtration rate, MDRD, Grade 4	0	0
Total neutrophils, Grade 3	1	0
Total neutrophils, Grade 4	1	2
Thrombocytopenia, Grade 3	1	0
Thrombocytopenia, Grade 4	0	0

41. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Treatment-emergent Division of AIDS (DAIDS) Toxicities at Week 48
Measure Description	The DAIDS toxicity table provides descriptive terminology for grading the severity of adult adverse events. Laboratory grades also provide ranges for each parameter. Grade 1: mild, Grade 2: moderate, Grade 3: severe, Grade 4: potentially life-threatening. LDL, low-density lipid; HDL, high-density lipid. Treatment emergent refers to any toxicity that was not present prior to the start of study drug treatment.
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Treatment-emergent Division of AIDS (DAIDS) Toxicities at Week 48 [units: participants]		
Cholesterol, Grade 3	7	1
Cholesterol, Grade 4	0	0
LDL cholesterol, Grade 3	9	3
LDL cholesterol, Grade 4	0	0
Non-HDL cholesterol, Grade 3	20	6
Non-HDL cholesterol, Grade 4	0	0
Triglycerides, Grade 3	3	0
Triglycerides, Grade 4	0	0
Alanine aminotransferase, Grade 3	2	4
Alanine aminotransferase, Grade 4	2	1
Aspartate aminotransferase, Grade 3	2	0
Aspartate aminotransferase, Grade 4	2	2
Alkaline phosphatase, Grade 3	0	1
Alkaline phosphatase, Grade 4	0	0
Total bilirubin Grade 3	1	0
Total bilirubin, Grade 4	0	0

	ABC/3TC FDC	TDF/FTC FDC
Creatinine kinase, Grade 3	0	2
Creatinine kinase, Grade 4	1	1
Phosphorus inorganic, Grade 3	3	1
Phosphorus inorganic, Grade 4	0	0
Lipase, Grade 3	5	1
Lipase, Grade 4	2	0
Hyperkalaemia, Grade 3	0	0
Hyperkalaemia, Grade 4	2	2
Glomerular filtration rate, MDRD, Grade 3	1	1
Glomerular filtration rate, MDRD, Grade 4	0	0
Total neutrophils, Grade 3	2	0
Total neutrophils, Grade 4	3	2
Thrombocytopenia, Grade 4	1	0
Thrombocytopenia, Grade 4	0	0

42. Secondary Outcome Measure:

Measure Title	Number of Participants With the Indicated Treatment-emergent Division of AIDS (DAIDS) Toxicities at Week 96
Measure Description	The DAIDS toxicity table provides descriptive terminology for grading the severity of adult adverse events. Laboratory grades also provide ranges for each parameter. Grade 1: mild, Grade 2: moderate, Grade 3: severe, Grade 4: potentially life-threatening. LDL, low-density lipid; HDL, high-density lipid. Treatment emergent refers to any toxicity that was not present prior to the start of study drug therapy.
Time Frame	Week 96
Safety Issue?	No

Analysis Population Description
Safety Population

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With the Indicated Treatment-emergent Division of AIDS (DAIDS) Toxicities at Week 96 [units: participants]		
Cholesterol, Grade 3	9	1
Cholesterol, Grade 4	0	0
LDL cholesterol, Grade 3	13	5
LDL cholesterol, Grade 4	0	0
Non-HDL cholesterol, Grade 3	22	5
Non-HDL cholesterol, Grade 4	0	0
Triglycerides, Grade 3	2	0
Triglycerides, Grade 4	1	0
Alanine aminotransferase, Grade 3	2	4
Alanine aminotransferase, Grade 4	2	1
Aspartate aminotransferase, Grade 3	2	1
Aspartate aminotransferase, Grade 4	2	2
Alkaline phosphatase, Grade 3	0	1
Alkaline phosphatase, Grade 4	0	0
Total bilirubin, Grade 3	1	0
Total bilirubin, Grade 4	0	0
Creatinine kinase, Grade 3	0	2
Creatinine kinase, Grade 4	1	2

	ABC/3TC FDC	TDF/FTC FDC
Phosphorus inorganic, Grade 3	4	3
Phosphorus inorganic, Grade 4	0	0
Lipase, Grade 3	6	2
Lipase, Grade 4	4	2
Hyperkalaemia, Grade 3	0	0
Hyperkalaemia, Grade 4	2	0
Glomerular filtration rate, MDRD, Grade 3	1	1
Glomerular filtration rate, MDRD, Grade 4	0	0
Total neutrophils, Grade 3	3	1
Total neutrophils, Grade 4	5	3
Thrombocytopenia, Grade 3	1	0
Thrombocytopenia, Grade 4	0	0

43. Secondary Outcome Measure:

Measure Title	Number of Participants With HIV-1 RNA <50 Copies/Milliliter (c/mL) and 400 c/mL at Week 24
Measure Description	HIV-1 RNA level (viral load) is a strong predictor of the rate of HIV disease progression. It was measured from plasma (participant blood samples) taken at all visits throughout the study. HIV, human immunodeficiency virus; RNA, ribonucleic acid. Viral load is a measure of the severity of the HIV infection.
Time Frame	Week 24
Safety Issue?	No

Analysis Population Description

ITT-E Population. Failures and missing values are derived according to the Time to Loss of Virologic Response (TLOVR) Food and Drug Administration (FDA) algorithm.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With HIV-1 RNA <50 Copies/ Milliliter (c/mL) and 400 c/mL at Week 24 [units: participants]		
<50 copies/mL	126	144
<400 copies/mL	147	168

44. Secondary Outcome Measure:

Measure Title	Number of Participants With HIV-1 RNA <50 Copies/Milliliter (c/mL) and 400 c/mL at Week 48
Measure Description	HIV-1 RNA level (viral load) is a strong predictor of the rate of HIV disease progression. It was measured from plasma (participant blood samples) taken at all visits throughout the study. HIV, human immunodeficiency virus; RNA, ribonucleic acid. Viral load is a measure of the severity of the HIV infection.
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population. Failures and missing values are derived according to the Time to Loss of Virologic Response (TLOVR) Food and Drug Administration (FDA) algorithm.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With HIV-1 RNA <50 Copies/ Milliliter (c/mL) and 400 c/mL at Week 48 [units: participants]		

	ABC/3TC FDC	TDF/FTC FDC
<50 copies/mL	121	145
<400 copies/mL	130	151

45. Secondary Outcome Measure:

Measure Title	Number of Participants With HIV-1 RNA <50 Copies/Milliliter (c/mL) and 400 c/mL at Week 96
Measure Description	HIV-1 RNA level (viral load) is a strong predictor of the rate of HIV disease progression. It was measured from plasma (participant blood samples) taken at all visits throughout the study. HIV, human immunodeficiency virus; RNA, ribonucleic acid. Viral load is a measure of the severity of the HIV infection.
Time Frame	Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population. Failures and missing values are derived according to the Time to Loss of Virologic Response (TLOVR) Food and Drug Administration (FDA) algorithm.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	192	193
Number of Participants With HIV-1 RNA <50 Copies/ Milliliter (c/mL) and 400 c/mL at Week 96 [units: participants]		
<50 copies/mL	98	113
<400 copies/mL	110	126

46. Secondary Outcome Measure:

Measure Title	Change From Baseline in Cluster Difference 4 (CD4+) Cell Count at Week 24
Measure Description	CD4+ counts are used to monitor the progression of HIV disease and the strength of the immune system. The number of CD4+ cells decreases as HIV disease progresses. Cell counts were measured from participant blood samples taken throughout the study.
Time Frame	Baseline, Week 24
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 24.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	153	172
Change From Baseline in Cluster Difference 4 (CD4+) Cell Count at Week 24 [units: cells/millimeters cubed (mm^3)] Median (Inter-Quartile Range)	110.0 (50.0 to 180.0)	100.0 (45.0 to 150.0)

47. Secondary Outcome Measure:

Measure Title	Change From Baseline in Cluster Difference 4 (CD4+) Cell Count at Week 48
Measure Description	CD4+ counts are used to monitor the progression of HIV disease and the strength of the immune system. The number of CD4+ cells decreases as HIV disease progresses. Cell counts were measured from participant blood samples taken throughout the study.
Time Frame	Baseline, Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 48.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	136	156
Change From Baseline in Cluster Difference 4 (CD4+) Cell Count at Week 48 [units: cells/mm^3] Median (Inter-Quartile Range)	150.0 (95.0 to 270.0)	150.0 (80.0 to 215.0)

48. Secondary Outcome Measure:

Measure Title	Change From Baseline in Cluster Difference 4 (CD4+) Cell Count at Week 96
Measure Description	CD4+ counts are used to monitor the progression of HIV disease and the strength of the immune system. The number of CD4+ cells decreases as HIV disease progresses. Cell counts were measured from participant blood samples taken throughout the study.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	110	128
Change From Baseline in Cluster Difference 4 (CD4+) Cell Count at Week 96 [units: cells/mm^3] Median (Inter-Quartile Range)	235.0 (130.0 to 390.0)	220.0 (150.0 to 315.0)

49. Secondary Outcome Measure:

Measure Title	Number of Participants Classified as Protocol-defined Failures With Treatment-emergent Resistance to Study Drug in the Indicated Viruses at Week 96
Measure Description	Viral resistance was measured using blood samples collected from participants throughout the study. NRTI, nucleoside reverse transcriptase inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor. Virological failure was defined as any one of: participant does not achieve a 1 log10 copies (cop)/mL decrease in plasma HIV-1 RNA by Week (Wk) 4, or has two consecutive plasma HIV-1 RNA measures >=400 cop/mL separated by at least 2-4 wk after being previously <=400 cop/mL on/after Wk 4, or has two consecutive plasma HIV-1 RNA measures >400 cop/mL separated by at least 2-4 wk on/after Wk 24.
Time Frame	Week 96
Safety Issue?	No

Analysis Population Description

On-Treatment Resistance: all participants who fulfilled the definition of protocol-defined virological failure (VF) who had paired baseline and VF genotypic data for analysis. One ABC/3TC participant took prohibited medication that potentially lowered efavirenz levels just prior to VF, allowing for the emergence of unexpected NRTI resistance.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	7	3

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Classified as Protocol-defined Failures With Treatment-emergent Resistance to Study Drug in the Indicated Viruses at Week 96 [units: participants]		
Any treatment-emergent mutation	4	0
NRTI	4	0
NNRTI	2	0

50. Secondary Outcome Measure:

Measure Title	Number of Participants Who Indicated "Yes" or "No" to the Question of Whether Unplanned Healthcare Resources Were Utilized
Measure Description	Participants were asked at each visit whether or not they utilized unplanned healthcare resources.
Time Frame	Baseline to Week 96
Safety Issue?	No

Analysis Population Description

ITT-E Population. The number of participants analyzed differed by visit because some had withdrawn during the study and some did not have an assessment performed.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	178	183
Number of Participants Who Indicated "Yes" or "No" to the Question of Whether Unplanned Healthcare Resources Were Utilized [units: participants]		

	ABC/3TC FDC	TDF/FTC FDC
Week 4, Yes, n=178, 183	60	49
Week 4, No, n=178, 183	118	134
Week 12, Yes, n=162, 177	56	47
Week 12, No, n=162, 177	106	130
Week 24, Yes, n=156, 173	70	59
Week 24, No, n=156, 173	86	114
Week 36, Yes, n=148, 169	48	50
Week 36, No, n=148, 169	100	119
Week 48, Yes, n=137, 161	44	36
Week 48, No, n=137, 161	93	125
Week 60, Yes, n=129, 148	47	44
Week 60, No, n=129, 148	82	104
Week 72, Yes, n=126, 139	48	40
Week 72, No, n=126, 139	78	99
Week 84, Yes, n=121, 136	34	24
Week 84, No, n=121, 136	87	108
Week 96, Yes, n=113, 135	30	17
Week 96, No, n=113, 135	83	118

51. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in Albumin as a Ratio to Urine Creatinine at Week 96
Measure Description	Renal biomarkers were analyzed using urine samples collected from participants at baseline and Week 96. Renal biomarkers may be an indicator of various aspects of kidney function. The ratio was calculated by dividing the change from baseline albumin value by the urine creatinine value. Albumin is measured in milligrams per millimole (mg/mmol).
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Biomarker Population: all randomized participants who received at least one dose of study medication and had at least one parameter measured at Baseline and at least one post-baseline visit. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	103	120
Exploratory Analysis of Change From Baseline in Albumin as a Ratio to Urine Creatinine at Week 96 [units: ratio] Geometric Mean (95% Confidence Interval)	0.872 (0.716 to 1.062)	0.973 (0.806 to 1.174)

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in Albumin as a Ratio to Urine Creatinine at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3025
	Comments	The model includes the following covariates: treatment, age, baseline biomarker value, and gender.
	Method	ANOVA
	Comments	Estimates are calculated from an ANOVA model. Parameters are analyzed based on log transformed data.

52. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in Beta 2 Microglobulin (B2M) as a Ratio to Urine Creatinine at Week 96

Measure Description	Renal biomarkers were analyzed using urine samples collected from participants at baseline and Week 96. Renal biomarkers may be an indicator of various aspects of kidney function. The ratio was calculated by dividing the change from baseline B2M value by the urine creatinine value. B2M, beta 2 microglobulin (measured in mg/mmol).
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	87	105
Exploratory Analysis of Change From Baseline in Beta 2 Microglobulin (B2M) as a Ratio to Urine Creatinine at Week 96 [units: ratio] Geometric Mean (95% Confidence Interval)	0.542 (0.370 to 0.792)	0.984 (0.684 to 1.416)

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in Beta 2 Microglobulin (B2M) as a Ratio to Urine Creatinine at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	The model includes the following covariates: treatment, age, baseline biomarker value, baseline CD4, and gender.
	Method	ANOVA

	Comments	Estimates are calculated from an ANOVA model. Parameters are analyzed based on log transformed data.

53. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in N-acetyl-B-glucosaminidase (NAG) as a Ratio to Urine Creatinine at Week 96
Measure Description	Renal biomarkers were analyzed using urine samples collected from participants at baseline and Week 96. Renal biomarkers may be an indicator of various aspects of kidney function. The ratio was calculated by dividing the change from baseline NAG value by the urine creatinine value. NAG, N-acetyl-B-glucosaminidase (measured in micromoles per hour per millimole [umol/h/mmol]).
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Biomarker Population: all randomized participants who received at least one dose of study medication and had at least one parameter measured at Baseline and at least one post-baseline visit. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	103	120
Exploratory Analysis of Change From Baseline in N-acetyl-B-glucosaminidase (NAG) as a Ratio to Urine Creatinine at Week 96 [units: ratio] Geometric Mean (95% Confidence Interval)	0.868 (0.774 to 0.974)	0.939 (0.844 to 1.044)

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in N-acetyl-B-glucosaminidase (NAG) as a Ratio to Urine Creatinine at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]

	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3323
	Comments	The model includes the following covariates: treatment, age, and baseline biomarker value.
	Method	ANOVA
	Comments	Estimates are calculated from an ANOVA model. Parameters are analyzed based on log transformed data.

54. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in Retinol Binding Protein (RBP) as a Ratio to Urine Creatinine at Week 96
Measure Description	Renal biomarkers were analyzed using urine samples collected from participants at baseline and Week 96. Renal biomarkers may be an indicator of various aspects of kidney function. The ratio was calculated by dividing the change from baseline RBP value by the urine creatinine value. RBP, retinol binding protein (measured in micrograms per millimole [ug/mmol]).
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Biomarker Population: all randomized participants who received at least one dose of study medication and had at least one parameter measured at Baseline and at least one post-baseline visit. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	103	120
Exploratory Analysis of Change From Baseline in Retinol Binding Protein (RBP) as a Ratio to Urine Creatinine at Week 96	1.099 (0.882 to 1.369)	1.550 (1.247 to 1.927)

	ABC/3TC FDC	TDF/FTC FDC
[units: ratio] Geometric Mean (95% Confidence Interval)		

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in Retinol Binding Protein (RBP) as a Ratio to Urine Creatinine at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	The model includes the following covariates: treatment, baseline biomarker value, baseline CD4, and gender.
	Method	ANOVA
	Comments	Estimates are calculated from an ANOVA model. Parameters are analyzed based on log transformed data.

55. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in Procollagen Type 1 Amino-terminal Propeptide (P1NP) at Week 96
Measure Description	P1NP is a bone biomarker that was analyzed using blood samples collected from participants at baseline and Week 96. Bone biomarkers may be an indicator of bone turnover.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Biomarker Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	94	114
Exploratory Analysis of Change From Baseline in Procollagen Type 1 Amino-terminal Propeptide (P1NP) at Week 96 [units: micrograms per Liter (ug/L)] Geometric Mean (95% Confidence Interval)	1.2 (1.1 to 1.2)	1.4 (1.3 to 1.5)

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in Procollagen Type 1 Amino-terminal Propeptide (P1NP) at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	<0.0001
	Comments	The model includes the following covariates: treatment, age, and baseline biomarker value.
	Method	ANOVA
	Comments	Estimates are calculated from ana ANOVA model. Parameters are analyzed based on log transformed data.

56. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in Type 1 Collagen Cross-linked C-telopeptide at Week 96
Measure Description	Bone biomarkers were analyzed using blood samples collected from participants at baseline and Week 96. Bone biomarkers may be an indicator of bone turnover.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Biomarker Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	94	114
Exploratory Analysis of Change From Baseline in Type 1 Collagen Cross-linked C-telopeptide at Week 96 [units: nanograms per Liter (ng/L)] Geometric Mean (95% Confidence Interval)	89.9 (25.1 to 154.7)	203.6 (143.3 to 264.0)

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in Type 1 Collagen Cross-linked C-telopeptide at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0019
	Comments	The model includes the following covariates: treatment, baseline biomarker value, and gender.
	Method	ANOVA
	Comments	Estimates are calculated from an ANOVA model.

57. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in Osteocalcin at Week 96
Measure Description	Bone biomarkers were analyzed using blood samples collected from participants at baseline and Week 96. Bone biomarkers may be an indicator of bone turnover.
Time Frame	Baseline, Week 96

Safety Issue?	No

Analysis Population Description

Safety Biomarker Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	94	114
Exploratory Analysis of Change From Baseline in Osteocalcin at Week 96 [units: ug/L] Geometric Mean (95% Confidence Interval)	3.01 (0.87 to 5.14)	5.79 (3.68 to 7.90)

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in Osteocalcin at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0019
	Comments	The model includes the following covariates: treatment, age, baseline biomarker value, and baseline CD4.
	Method	ANOVA
	Comments	Estimates are calculated from an ANOVA model.

58. Other Pre-specified Outcome Measure:

Measure Title	Exploratory Analysis of Change From Baseline in Bone Specific Alkaline Phosphatase (BSAP) at Week 96

Measure Description	Bone biomarkers were analyzed using blood samples collected from participants at baseline and Week 96. Bone biomarkers may be an indicator of bone turnover.
Time Frame	Baseline, Week 96
Safety Issue?	No

Analysis Population Description

Safety Biomarker Population. Some participants had withdrawn by Week 96.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Measured Values

	ABC/3TC FDC	TDF/FTC FDC
Number of Participants Analyzed	93	114
Exploratory Analysis of Change From Baseline in Bone Specific Alkaline Phosphatase (BSAP) at Week 96 [units: ug/L] Geometric Mean (95% Confidence Interval)	1.111 (-0.426 to 2.649)	2.542 (1.028 to 4.056)

Statistical Analysis 1 for Exploratory Analysis of Change From Baseline in Bone Specific Alkaline Phosphatase (BSAP) at Week 96

Statistical Analysis Overview	Comparison Groups	ABC/3TC FDC, TDF/FTC FDC
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0266
	Comments	The model includes the following covariates: treatment, baseline biomarker value, and baseline CD4.
	Method	ANOVA

	Comments	Estimates are calculated from an ANOVA model.

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Serious adverse events (SAEs) and adverse events (AEs) were collected in the Safety Population, comprised of all randomized participants who received at least one dose of study medication.

Reporting Groups

	Description
ABC/3TC FDC	Abacavir (ABC) 600 mg/lamivudine (3TC) 300 mg fixed dose combination (FDC) once daily (QD) plus 600 mg efavirenz QD
TDF/FTC FDC	Tenofovir (TDF) 300 mg/emtricitabine (FTC) 200 mg FDC once daily (QD) plus 600 mg efavirenz QD

Serious Adverse Events

	ABC/3TC FDC	TDF/FTC FDC
	Affected/At Risk (%)	Affected/At Risk (%)
Total	31/192 (16.15%)	20/193 (10.36%)
Blood and lymphatic system disorders		
Neutropenia [A] †	1/192 (0.52%)	0/193 (0%)
Cardiac disorders		
Acute myocardial infarction [A] †	0/192 (0%)	1/193 (0.52%)
Congenital, familial and genetic disorders		
Porphyria non-acute [A] †	1/192 (0.52%)	0/193 (0%)
Endocrine disorders		
Goitre [A] †	0/192 (0%)	1/193 (0.52%)
Gastrointestinal disorders		
Abdominal hernia [A] †	1/192 (0.52%)	0/193 (0%)
Diverticulum [A] †	1/192 (0.52%)	0/193 (0%)

	ABC/3TC FDC	TDF/FTC FDC
	Affected/At Risk (%)	Affected/At Risk (%)
Gastritis [A] †	1/192 (0.52%)	0/193 (0%)
Rectal haemorrhage [A] †	1/192 (0.52%)	0/193 (0%)
General disorders		
Pyrexia [A] †	1/192 (0.52%)	0/193 (0%)
Hepatobiliary disorders		
Cholecystitis [A] †	1/192 (0.52%)	0/193 (0%)
Cholelithiasis [A] †	1/192 (0.52%)	0/193 (0%)
Cholestasis [A] †	0/192 (0%)	1/193 (0.52%)
Cytolytic hepatitis [A] †	0/192 (0%)	1/193 (0.52%)
Hepatitis [A] †	0/192 (0%)	1/193 (0.52%)
Immune system disorders		
Drug hypersensitivity [A] †	5/192 (2.6%)	1/193 (0.52%)
Hypersensitivity [A] †	3/192 (1.56%)	0/193 (0%)
Immune reconstitution syndrome [A] †	2/192 (1.04%)	0/193 (0%)
Infections and infestations		
Abscess limb [A] †	0/192 (0%)	1/193 (0.52%)
Endocarditis [A] †	0/192 (0%)	1/193 (0.52%)
Erysipelas [A] †	1/192 (0.52%)	0/193 (0%)
Eye infection toxoplasmal [A] †	1/192 (0.52%)	0/193 (0%)
Gastroenteritis [A] †	2/192 (1.04%)	0/193 (0%)
Herpes Zoster [A] †	1/192 (0.52%)	0/193 (0%)
Lower respiratory tract infection [A] †	1/192 (0.52%)	1/193 (0.52%)
Pneumonia [A] †	5/192 (2.6%)	1/193 (0.52%)

	ABC/3TC FDC	TDF/FTC FDC
	Affected/At Risk (%)	Affected/At Risk (%)
Pulmonary tuberculosis [A] †	1/192 (0.52%)	1/193 (0.52%)
Scrotal abscess [A] †	1/192 (0.52%)	0/193 (0%)
Staphylococcal abscess [A] †	0/192 (0%)	1/193 (0.52%)
Tuberculosis [A] †	1/192 (0.52%)	0/193 (0%)
Viral infection [A] †	1/192 (0.52%)	0/193 (0%)
Injury, poisoning and procedural complications		
Accidental overdose [A] †	1/192 (0.52%)	0/193 (0%)
Ankle fracture [A] †	0/192 (0%)	1/193 (0.52%)
Forearm fracture [A] †	0/192 (0%)	1/193 (0.52%)
Humerus fracture [A] †	0/192 (0%)	1/193 (0.52%)
Meniscus lesion [A] †	1/192 (0.52%)	0/193 (0%)
Investigations		
Cardiac murmur [A] †	1/192 (0.52%)	0/193 (0%)
Metabolism and nutrition disorders		
Dehydration [A] †	1/192 (0.52%)	0/193 (0%)
Musculoskeletal and connective tissue disorders		
Back pain [A] †	0/192 (0%)	1/193 (0.52%)
Osteoarthritis [A] †	0/192 (0%)	1/193 (0.52%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Burkitt's lymphoma [A] †	0/192 (0%)	1/193 (0.52%)
Lymphoma [A] †	0/192 (0%)	1/193 (0.52%)
Thymoma [A] †	1/192 (0.52%)	0/193 (0%)
Nervous system disorders		

	ABC/3TC FDC	TDF/FTC FDC
	Affected/At Risk (%)	Affected/At Risk (%)
Convulsion [A] †	1/192 (0.52%)	0/193 (0%)
Transient ischaemic attack [A] †	0/192 (0%)	1/193 (0.52%)
Psychiatric disorders		
Acute stress disorder [A] †	0/192 (0%)	1/193 (0.52%)
Apathy [A] †	0/192 (0%)	1/193 (0.52%)
Renal and urinary disorders		
Renal failure [A] †	1/192 (0.52%)	0/193 (0%)
Reproductive system and breast disorders		
Epididymitis [A] †	0/192 (0%)	1/193 (0.52%)
Respiratory, thoracic and mediastinal disorders		
Asthma [A] †	1/192 (0.52%)	0/193 (0%)
Skin and subcutaneous tissue disorders		
Rash maculo-papular [A] †	1/192 (0.52%)	0/193 (0%)

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

Other Adverse Events

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

	ABC/3TC FDC	TDF/FTC FDC
	Affected/At Risk (%)	Affected/At Risk (%)
Total	172/192 (89.58%)	175/193 (90.67%)
Gastrointestinal disorders		
Diarrhoea [A] †	36/192 (18.75%)	27/193 (13.99%)
Nausea [A] †	17/192 (8.85%)	16/193 (8.29%)
Vomiting [A] †	12/192 (6.25%)	11/193 (5.7%)

	ABC/3TC FDC	TDF/FTC FDC
	Affected/At Risk (%)	Affected/At Risk (%)
General disorders		
Fatigue [A] †	14/192 (7.29%)	16/193 (8.29%)
Infections and infestations		
Influenza [A] †	12/192 (6.25%)	14/193 (7.25%)
Nasopharyngitis [A] †	39/192 (20.31%)	36/193 (18.65%)
Investigations		
Bone density decreased [A] †	5/192 (2.6%)	15/193 (7.77%)
Musculoskeletal and connective tissue disorders		
Back pain [A] †	11/192 (5.73%)	16/193 (8.29%)
Nervous system disorders		
Dizziness [A] †	48/192 (25%)	48/193 (24.87%)
Headache [A] †	17/192 (8.85%)	29/193 (15.03%)
Psychiatric disorders		
Abnormal dreams [A] †	23/192 (11.98%)	22/193 (11.4%)
Depression [A] †	14/192 (7.29%)	15/193 (7.77%)
Insomnia [A] †	21/192 (10.94%)	18/193 (9.33%)
Sleep disorder [A] †	14/192 (7.29%)	16/193 (8.29%)
Respiratory, thoracic and mediastinal disorders		
Cough [A] †	17/192 (8.85%)	13/193 (6.74%)
Skin and subcutaneous tissue disorders		
Rash [A] †	18/192 (9.38%)	20/193 (10.36%)

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

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

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

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

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