ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 05/31/2012

ClinicalTrials.gov ID: NCT00450580

Study Identification

Unique Protocol ID:	APV109141
Brief Title:	HIV-1 Infection Study of Once a Day Versus Twice a Day Protease Inhibitor in Antiretroviral Treatment Naive Adults
Official Title:	Study of Once-Daily Versus Twice-Daily Fosamprenavir Plus Ritonavir, Administered With Abacavir/Lamivudine Once-Daily in Antiretroviral-Naive HIV-1 Infected Adult Subjects.
Secondary IDs:	

Study Status

Record Verification:	April 2012
Overall Status:	Completed
Study Start:	March 2007
Primary Completion:	August 2008 [Actual]
Study Completion:	August 2008 [Actual]

Sponsor/Collaborators

Sponsor:	ViiV Healthcare
Responsible Party:	Sponsor
Collaborators:	GlaxoSmithKline

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: APV109141 Board Name: Azienda Ospedaliera Pugliese Ciaccio - Comitato Etico Board Affiliation: No affiliation Phone: Email: cometico@aocatanzaro.it
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	United Kingdom: Medicines and Healthcare Products Regulatory Agency Belgium: Federal Agency for Medicinal Products and Health Products Spain: Ministry of Health and Consumption France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Romania: National Medicines Agency Italy: The Italian Medicines Agency

Study Description

Brief Summary:	This is a Phase IIIB, 48 Week, multicentre, randomized, open-label, parallel group study comparing the safety and efficacy of fosamprenavir plus ritonavir 1400mg/100mg once-daily to fosamprenavir plus ritonavir 700mg/100mg twice-daily, both administered with abacavir/lamivudine 600mg/300mg once-daily in antiretroviral-naive HIV-1 infected adults. This study utilizes a group-sequential design with two stages: 1) an interim 24 week cohort analysis of approximately 200 subjects and 2) if study continuation criteria are met at this interim analysis, further enrolment of an additional 528 subjects, followed over a minimum of 48 weeks. The objectives of the study are to demonstrate 1) non-inferior antiviral activity of fosamprenavir/ritonavir 1400mg/100mg QD compared to fosamprenavir/ritonavir 700mg/100mg BID and 2) a superior fasting non-HDL lipid profile in subjects receiving fosamprenavir/ritonavir 1400mg/100mg QD.
Detailed Description:	

Conditions

Conditions:	Infection, Human Immunodeficiency Virus I HIV-1 Infection
Keywords:	protease inhibitor, HIV-1, Fosamprenavir, non-HDL cholesterol ritonavir,

naive,

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Open Label
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	212 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Arm A Fosamprenavir/ritonavir 1400mg/100mg QD + ABC/3TC FDC 600/300mg QD	Drug: fosamprenavir/ritonavir Fosamprenavir (FPV, TELZIR) is currently licensed in Europe for twice daily (BID) dosing in combination with ritonavir (RTV, Norvir) as a boosting agent Other Names: • fosamprenavir/ritonavir
Active Comparator: Arm B Fosamprenavir/ritonavir 700mg/100mg BID + ABC/3TC FDC 600/300mg QD	Drug: fosamprenavir/ritonavir Fosamprenavir (FPV, TELZIR) is currently licensed in Europe for twice daily (BID) dosing in combination with ritonavir (RTV, Norvir) as a boosting agent Other Names: • fosamprenavir/ritonavir

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

- Subject is ≥18 years of age.
- Subject is antiretroviral-naïve (defined as having ≤14 days of prior therapy with any antiretroviral agent).
- Subject has plasma HIV-1 RNA ≥1,000 copies/mL at screening.
- 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 (serum b-HCG) 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 permitted in 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). All subjects participating in the study should be counselled on the practice of safer sex.
- Prior to randomization, subjects entering Stage 2 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. Subjects may be enrolled provided they are receiving treatment for such infections and are clinically improving at the Baseline visit.
- 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 any serious medical condition (such as pancreatitis, diabetes, congestive heart failure, cardiomyopathy or other cardiac dysfunction) which in the opinion of the Investigator would compromise the safety of the subject.
- Subject has a pre-existing mental, physical, or substance abuse disorder which, in the opinion of the Investigator, may interfere with the subject’s ability to comply with the dosing schedule and protocol evaluations and assessments.

- Subject has a history of inflammatory bowel disease or intestinal malignancy, intestinal ischemia, malabsorption, or other gastrointestinal dysfunction, which, in the opinion of the Investigator, may interfere with drug absorption or render the subject unable to take oral medication.
- Subject has any acute laboratory abnormality at screening, which, in the opinion of the Investigator, would preclude the subject's participation in the study of an investigational compound. If subjects are found to have an acute Grade 4 laboratory abnormality at screening, this test may be repeated once within the 45-day screening window. Any verified Grade 4 laboratory abnormality would exclude a subject from study participation.
- Subject has an estimated creatinine clearance < 50 mL/min via the Cockcroft-Gault method [Cockcroft, 1976]. This test may be repeated once within the 45-day screening window.

NOTE: Creatinine clearance should be estimated using the following formula:

For serum creatinine concentration in mg/dL:

For serum creatinine concentration in µmol/L:

- Alanine aminotransferase (ALT) >5 times the upper limit of normal (ULN) or hepatic impairment as determined by Child-Pugh Score ≥ 5.
- Subject is receiving, or has received within 90 days prior to screen, any lipid lowering agent, including drugs from the following classes: HMG-CoA reductase inhibitors (statins), niacin, fibrates, bile acid sequestrants, and/or fish oil supplements. Subjects anticipated to require initiation of therapy with these agents within 12 weeks of Baseline are not eligible to participate.
- Subject has received treatment with radiation therapy or cytotoxic chemotherapeutic agents within 28 days prior to Screening, or has an anticipated need for these agents within the study period.
- 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 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:
    - Amiodarone, astemizole, bepridil, cisapride, dihydroergotamine, ergonovine, ergotamine, flecainide, halofantrine, lidocaine, lovastatin, methylergonovine, midazolam, pimozide, propafenone, quinidine, simvastatin, terfenadine, triazolam.
    - Carbamazepine, dexamethasone, phenobarbital, phenytoin, primidone, rifampin, St Johns Wort (Hypericum perforatum), troglitazone.
    - Systemic interleukins or interferons.
- Subject has a history of allergy to any of the investigational products or any excipients therein.
- Subject has evidence of genotypic (as defined by the current ANRS AC-11 algorithm) resistance at screening or prior documented evidence of genotypic and/or phenotypic (above threshold for reduced susceptibility) resistance to amprenavir/ritonavir, abacavir or lamivudine.
- Subjects recruited at sites in France will be excluded if:
    - The subject is not affiliated with or a beneficiary of a social security.
    - 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. Notwithstanding these minimum inclusion and exclusion criteria, investigators are urged to follow country specific guidelines where they exist when making decisions about subjects who are eligible for study participation.

Contacts/Locations

Study Officials: GSK Clinical Trials
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References

Citations: Ross LL, Robinson MD, Carosi G, et al. Impact of HIV subtype on response and resistance in antiretroviral-naïve adults comparing treatment with once daily versus twice daily Ritonavir boosted Fosamprenavir in combination with Abacavir/ Lamivudine. [Drugs Ther Stud]. 2012;2(e1):

Carosi G, Lazzarin A, Stellbrink H, et al. Efficacy and Safety of Fosamprenavir + Ritonavir (FPV/RTV) 700mg/100mg Twice Daily (BID) Versus FPV/RTV 1400mg/100mg Once Daily (QD) with ABC/3TC QD over 24 Weeks. Abstract H-1244, 48th Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington, DC, 2008.

Links:

Study Data/Documents:

Study Results

Participant Flow

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Overall Study

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Started	106	106
Completed	90	90

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Not Completed	16	16
Adverse Event	5	7
Lost to Follow-up	4	5
Withdrawal by Subject	2	2
Protocol Violation	1	1
Protocol-defined virologic failure	1	0
Could not comply with scheduled visits	1	0
Patient went to Brazil	1	0
Patient could not swallow Norvir	1	0
Withdrawal due to pregnancy	0	1

Baseline Characteristics

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Baseline Measures

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	Total
Number of Participants	106	106	212
Age, Customized [units: years] Mean (Full Range)	37 (18 to 70)	38 (19 to 69)	38 (18 to 70)
Gender, Male/Female [units: participants]			
Female	27	29	56
Male	79	77	156

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	Total
Race/Ethnicity, Customized [units: participants]			
African American/African heritage	23	22	45
American Indian/Alaskan native	3	3	6
Asian - South East Asian	2	2	4
White - Arabic/North African	1	1	2
White - White/Caucasian/ European	75	78	153
Mixed race	2	0	2

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With HIV-1 RNA <400 and >=400 Copies/mL Over 48 Weeks
Measure Description	A blood sample was drawn to determine the amount of HIV-1 RNA virus in copies/mL at week 48. The percentage of participants with HIV-1 RNA <400 copies/mL at Week 48 was determined by the Time to Loss Of Virologic Response (TLOVR) algorithm.
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description

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

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Measured Values

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Number of Participants Analyzed	106	106
Percentage of Participants With HIV-1 RNA <400 and >=400 Copies/mL Over 48 Weeks [units: Percentage of participants]		
HIV-1 RNA <400 copies/mL	81	82
HIV-1 RNA >=400 copies/mL	19	18

Statistical Analysis 1 for Percentage of Participants With HIV-1 RNA <400 and >=400 Copies/mL Over 48 Weeks

Statistical Analysis Overview	Comparison Groups	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q, FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
	Comments	[Not specified]
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	Non-inferiority can be concluded if the lower bound of a two-sided 95% confidence interval for the difference in response rates between the two treatment arms is greater than -12%.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-0.9
	Confidence Interval	(2-Sided) 95% -11.4 to 9.5
	Estimation Comments	[Not specified]

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With HIV-1 RNA <50 and >=50 Copies/mL by Visit Over 48 Weeks
Measure Description	A blood sample was drawn to determine the amount of HIV-1 RNA virus in copies/mL at week 48. The percentage of participants with HIV-1 RNA <50 copies/mL at Week 48 was determined by the TLOVR algorithm
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description
ITT-E Population

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Measured Values

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Number of Participants Analyzed	106	106
Percentage of Participants With HIV-1 RNA <50 and >=50 Copies/mL by Visit Over 48 Weeks [units: Percentage of participants]		
HIV-1 RNA <50 copies/mL	76	77
HIV-1 RNA >=50 copies/mL	24	23

3. Secondary Outcome Measure:

Measure Title	Number of Participants With HIV-1 RNA <400 Copies/mL (Primary Endpoint) at Week 48 Categorised by Baseline Viral Load, TLOVR Analysis
Measure Description	The number of participants with HIV-1 RNA <400 copies/mL at Week 48 was determined (by analysis of blood draw) and categorised by baseline viral load (BVL).
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description
ITT-E Population

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily

	Description
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Measured Values

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Number of Participants Analyzed	106	106
Number of Participants With HIV-1 RNA <400 Copies/mL (Primary Endpoint) at Week 48 Categorised by Baseline Viral Load, TLOVR Analysis [units: Participants]		
<50000 cp/mL (n=35, 40)	26	37
>=50000 to <100000 cp/mL (n=21, 19)	18	15
>=100000 to <200000 cp/mL (n=25, 17)	21	11
>=200000 cp/mL (n=25, 30)	21	24

4. Secondary Outcome Measure:

Measure Title	Number of Participants With HIV-1 RNA <400 Copies/mL (Primary Endpoint) at Week 48 Categorised by Baseline CD4+ Count, TLOVR Analysis
Measure Description	The number of participants with HIV-1 RNA <400 copies/mL at week 48 was determined (by analysis of blood draw) and categorised by baseline CD4+ count.
Time Frame	Week 48
Safety Issue?	No

Analysis Population Description

ITT-E Population

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily

	Description
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Measured Values

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Number of Participants Analyzed	106	106
Number of Participants With HIV-1 RNA <400 Copies/mL (Primary Endpoint) at Week 48 Categorised by Baseline CD4+ Count, TLOVR Analysis [units: Participants]		
<150 cells/mm3 (n=24, 23)	18	16
>=150 to <250 cells/mm3 (n=29, 31)	24	26
>=250 to <350 cell/mm3 (n=29, 31)	23	26
>=350 cell/mm3 (n=24, 21)	21	19

5. Secondary Outcome Measure:

Measure Title	Change From Baseline in Non-HDL Cholesterol at Week 48
Measure Description	Blood samples were drawn to determine the non-HDL cholesterol levels at Week 48. The mean absolute change in non-HDL cholesterol was defined as the Week 48 levels minus levels at baseline.
Time Frame	Week 48
Safety Issue?	Yes

Analysis Population Description

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

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Measured Values

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Number of Participants Analyzed	77	80
Change From Baseline in Non-HDL Cholesterol at Week 48 [units: mmol/L (millimoles/Liter)] Mean (Standard Deviation)	1.10 (0.81)	1.26 (0.90)

6. Secondary Outcome Measure:

Measure Title	Number of Protocol-defined Virological Failures With Genotypic and Phenotypic Resistance Changes
Measure Description	A blood sample was drawn at the time of confirmation of virological failure, and mutations present in the virus were identified and compared to those found in the blood sample at baseline. New mutations were tabulated by drug class. RT, reverse transcriptase. Virological failure could occur anytime from Week 4 to Week 48.
Time Frame	Time to virologic failure; Week 4 up to Week 48
Safety Issue?	No

Analysis Population Description

Participants in the ITT-E Population who met the definition of virological failure

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Measured Values

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Number of Participants Analyzed	2	1
Number of Protocol-defined Virological Failures With Genotypic and Phenotypic Resistance Changes [units: Participants]		

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Treatment-Emergent Major HIV RT Mutations (M184V)	1	0
Treatment-Emergent Major HIV Protease Mutations	0	0

7. Secondary Outcome Measure:

Measure Title	Steady-state Levels of Amprenavir (APV) and Ritonavir (RTV) Ctau at Weeks 4, 12, and 24
Measure Description	Blood samples were drawn at Weeks 4, 12, and 24 to determine plasma concentrations (Ctau) of APV and RTV
Time Frame	Weeks 4, 12, and 24
Safety Issue?	No

Analysis Population Description

PK parameter (Ctau) Population – Participants in the ITT-E population who underwent PK sampling and had evaluable APV Ctau or RTV Ctau data

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Measured Values

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Number of Participants Analyzed	79	97
Steady-state Levels of Amprenavir (APV) and Ritonavir (RTV) Ctau at Weeks 4, 12, and 24 [units: micrograms/mL] Geometric Mean (95% Confidence Interval)		
Week 4 APV Ctau	1.11 (0.909 to 1.35)	1.99 (1.76 to 2.26)
Week 12 APV Ctau	0.913 (0.747 to 1.17)	1.87 (1.66 to 2.12)
Week 24 APV Ctau	1.08 (0.869 to 1.34)	2.00 (1.78 to 2.25)

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
Week 4 RTV Ctau	0.0369 (0.0264 to 0.0516)	0.166 (0.137 to 0.201)
Week 12 RTV Ctau	0.0285 (0.0215 to 0.0379)	0.175 (0.150 to 0.205)
Week 24 RTV Ctau	0.0363 (0.0241 to 0.0545)	0.170 (0.143 to 0.202)

8. Secondary Outcome Measure:

Measure Title	Study Endpoints for a Subset of Subjects Receiving Study Drug Beyond 48 Weeks
Measure Description	Adaptive two-stage design study up to 48 weeks. N=200, expanding to 728 if continuation criteria were achieved based on a 24-week interim analysis. The initial 200 participants would continue until the last subject of the expanded cohort reached 48 weeks and would constitute the subset. As continuation criteria were not achieved, the study did not proceed to the second stage, and full analysis was performed on the initial 200 participants only.
Time Frame	Up to 60 weeks
Safety Issue?	No

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	Fosamprenavir (FPV)/ritonavir (RTV) 1400 mg/100 mg once daily administered with abacavir/lamivudine fixed dose combination (ABC/3TC FDC) 600/300 mg once daily
FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD	FPV/RTV 700 mg/100 mg twice daily administered with ABC/3TC FDC 600/300 mg once daily

Serious Adverse Events

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
	Affected/At Risk (%)	Affected/At Risk (%)
Total	19/	18/
Blood and lymphatic system disorders		
Lymphadenopathy [A] †	0/106 (0%)	1/106 (0.94%)
Cardiac disorders		
Angina pectoris [A] †	1/106 (0.94%)	0/106 (0%)
Myocardial infarction [A] †	0/106 (0%)	1/106 (0.94%)
Gastrointestinal disorders		
Pancreatitis [A] †	1/106 (0.94%)	0/106 (0%)
Hepatobiliary disorders		
Hepatitis acute [A] †	0/106 (0%)	1/106 (0.94%)
Immune system disorders		
Drug Hypersensitivity [A] †	15/106 (14.15%)	8/106 (7.55%)
Immune reconstitution syndrome [A] †	0/106 (0%)	1/106 (0.94%)
Infections and infestations		
Atypical mycobacterial infection [A] †	0/106 (0%)	1/106 (0.94%)
Cat scratch disease [A] †	0/106 (0%)	1/106 (0.94%)
Hepatitis C [A] †	0/106 (0%)	1/106 (0.94%)
Mycobacterium avium complex infection [A] †	0/106 (0%)	1/106 (0.94%)
Pneumonia [A] †	2/106 (1.89%)	1/106 (0.94%)
Respiratory tract infection [A] †	0/106 (0%)	1/106 (0.94%)
Sepsis [A] †	1/106 (0.94%)	0/106 (0%)
Staphylococcal sepsis [A] †	0/106 (0%)	1/106 (0.94%)

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
	Affected/At Risk (%)	Affected/At Risk (%)
Superinfection [A] †	0/106 (0%)	1/106 (0.94%)
Investigations		
Alanine aminotransferase increased [A] †	0/106 (0%)	1/106 (0.94%)
Aspartate aminotransferase increased [A] †	1/106 (0.94%)	0/106 (0%)
Metabolism and nutrition disorders		
Diabetes mellitus inadequate control [A] †	1/106 (0.94%)	0/106 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Burkitt's lymphoma [A] †	1/106 (0.94%)	0/106 (0%)
Nervous system disorders		
Facial paresis [A] †	1/106 (0.94%)	0/106 (0%)
Psychiatric disorders		
Depression [A] †	0/106 (0%)	1/106 (0.94%)
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease [A] †	1/106 (0.94%)	0/106 (0%)
Lung disorder [A] †	0/106 (0%)	1/106 (0.94%)

† 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%

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
	Affected/At Risk (%)	Affected/At Risk (%)
Total	79/	72/
Gastrointestinal disorders		

	FPV/RTV 1400/100 mg Once Daily (QD) + ABC/3TC FDC 600/300 mg Q	FPV/RTV 700/100 mg BID + ABC/3TC FDC 600/300 mg QD
	Affected/At Risk (%)	Affected/At Risk (%)
Diarrhoea [A] †	45/106 (42.45%)	49/106 (46.23%)
Dyspepsia [A] †	5/106 (4.72%)	2/106 (1.89%)
Nausea [A] †	18/106 (16.98%)	9/106 (8.49%)
Vomiting [A] †	8/106 (7.55%)	5/106 (4.72%)
General disorders		
Fatigue [A] †	7/106 (6.6%)	6/106 (5.66%)
Immune system disorders		
Drug hypersensitivity [A] †	15/106 (14.15%)	8/106 (7.55%)
Infections and infestations		
Nasopharyngitis [A] †	18/106 (16.98%)	7/106 (6.6%)
Metabolism and nutrition disorders		
Hypercholesterolaemia [A] †	6/106 (5.66%)	8/106 (7.55%)
Hypertriglyceridaemia [A] †	2/106 (1.89%)	9/106 (8.49%)
Skin and subcutaneous tissue disorders		
Rash [A] †	11/106 (10.38%)	13/106 (12.26%)

† 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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