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Efficacy and Safety of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate in Asian Subjects with Human Immunodeficiency Virus 1 Infection: A Sub-Analysis of Phase 3 Clinical Trials

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The efficacy and safety of a single tablet regimen (STR) of elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (E/C/F/TDF) were analyzed in Phase 3 clinical trials in antiretroviral therapy (ART)-naïve and ART-experienced Asian subjects infected with human immunodeficiency virus (HIV)-1. Studies GS-US-236-102 and GS-US-236-103 were randomized, double-blind, placebo-controlled, 144-week studies conducted in ART-naïve subjects, comparing E/C/F/TDF versus efavirenz (EFV)/F/TDF or ritonavir-boosted atazanavir (ATV+RTV) plus emtricitabine/tenofovir DF (F/TDF), respectively. Studies GS-US-236-115 and GS-US-236-121 were randomized, open-label, 96-week long conducted in ART-experienced subjects, who switched to E/C/F/TDF from ritonavir-boosted protease inhibitors (PI+RTV)+F/TDF, or non-nucleoside reverse transcriptase inhibitors (NNRTI)+F/TDF regimens. The E/C/F/TDF appeared to have sustained efficacy and safety and was well tolerated in the small number of ART-naïve and ART-experienced Asian subjects..

Key Words: Human immunodeficiency virus; Antiretroviral therapy; Asian Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate

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The single tablet regimen (STR) containing elvitegravir, cobicistat, emtricitabine and tenofovir disoproxil fumarate (E/C/F/TDF) is a recommended regimen in the guidelines of the US Department of Health and Human Services and the European acquired immunodeficiency syndrome (AIDS) Clinical Society [1, 2]. In two Phase 3 randomized, double-blind, placebo-controlled clinical trials in ART-naïve adults infected with the human immunodeficiency virus (HIV)-1, E/C/F/TDF (n = 701) demonstrated non-inferior efficacy at week 48, 96, and 144 compared to the STR of efavirenz (EFV)/F/TDF (GS-US-236-0102, Study 102) and the ritonavir-boosted atazanavir (ATV+RTV) plus emtricitabine/tenofovir DF (F/TDF, GS-US-236-0103, Study 103) as well as favorable safety and tolerability [3-9]. Studies GS-US-236-115 (STRATEGY-PI) and GS-US-236-121 (STRATEGY-NNRTI) examined the efficacy, safety, and tolerability of switching to E/C/F/TDF from ritonavir-boosted protease inhibitors (PI+RTV)+ F/TDF or non-nucleoside reverse transcriptase inhibitors (NNRTI)+F/TDF regimens, respectively, in virologically suppressed (HIV-1 RNA <50 copies/mL), ART-experienced adult subjects [10-13]. At week 48 and 96, the STRATEGY-PI study showed that switching to E/C/F/TDF from a PI+RTV-based regimen was associated with significantly higher rates of virological success, lower triglyceride levels, and improvements in self-reported diarrhea and bloating [14]. The STRATEGY-NNRTI study showed the non-inferior efficacy of E/C/F/TDF versus re-

Table 1. Baseline characteristics: Asian subpopulation studies

Characteristic, % (n)	ART-naïve Studies 102 and 103		
	E/C/F/TDF (n=23)	EFV/F/TDF (n=10)	ATV+RTV+F/TDF (n=17)
Median Age, years (range)	33 (19-48)	32 (25-49)	35 (19-52)
Male	83 (19)	90 (9)	88 (15)
Asymptomatic HIV Infection	87 (20)	100 (10)	82 (14)
HBV : HCV Seropositive	0%:0%	10%: 0%	12%: 0%
Country of Enrollment			
USA	35 (8)	100 (10)	18 (3)
Thailand	30 (7)	0	24 (4)
Europe	26 (6)	0	6 (1)
Other[a]	9 (2)	0	53 (9)
Median HIV-1 RNA, log10c/mL	4.8	4.6	4.6
> 100,000 c/mL	35 (8)	30 (3)	24 (4)
Mean CD4+ T cell count, cells/mm^3, (range)	374 (220-570)	338 (152-653)	346 (51-507)
≤350	52 (12)	60 (6)	47 (8)
≤200	0	20 (2)	12 (2)
Median GFR by Cockcroft Gault, mL/min	100	93	105

Characteristics, % (n)	ART-experienced Studies 115 and 121			
	STRATEGY-PI		STRATEGY-NNRTI	
	E/C/F/TDF (n =7)	PI+RTV+ TVD (n =2)	E/C/F/TDF (n =4)	NNRTI+TVD (n =9)
Median Age, years (range)	33 (22-45)	48 (40-55)	45 (40-51)	38 (26-50)
Male	71 (5)	100 (2)	100 (4)	100 (9)
Asymptomatic HIV Infection	54 (4)	100 (2)	25 (1)	67 (6)
HBV : HCV Seropositive , n	0 : 0	0 : 1	0 : 0	1 : 0
Country of Enrollment				
USA	14 (1)	50 (1)	100 (4)	78 (7)
Europe	71 (5)	50 (1)	0	11 (1)
Other[b]	14 (1)	0	0	11 (1)
Mean CD4+ T cell count, cells/mm^3, (range)	548 (327-996)	478 (385-570)	402 (210-805)	592 (300-927)
≤350	14 (1)	0	75 (3)	22 (2)
≤200	0	0	25 (1)	0
Median GFR by Cockcroft Gault, mL/min	104	104	125	112

[a]Other: E/C/F/TDF; Australia (2); ATV+RTV+TVD; Australia (7); Canada (2).
[b]Other: E/C/F/TDF: Switzerland (1); NNRTI+TVD: Australia (1).
E, elvitegravir; C, cobicistat; F, emtricitabine; TDF, tenofovir disoproxil fumarate; EFV, efavirenz; ATV, atazanavir; RTV, ritonavir; PI, protease inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; GFR, glomerular filtration rate.

maining on the NNRTI+ F/TDF regimen, improvement in patient-reported outcomes (PROs) related to NNRTI-associated neuropsychiatric side effects, and greater treatment satisfaction scores [15]. There is limited data on the efficacy and safety of current antiretroviral therapies in Asian subjects infected with HIV-1. Here, we report a sub-analysis of E/C/F/TDF efficacy and safety data in Asian subjects enrolled in Studies 102 and 103 at week 144 as well as Studies 115 and 121 at week 96.

In the two ART-naïve studies, 1,408 subjects (E/C/F/TDF, n = 701 vs. EFV/FTC/TDF, n = 352 vs. ATV+RTV+ F/TDF, n = 355) were enrolled and received at least one dose of a study drug. In the two studies with ART-experienced, virologically suppressed subjects, 867 (Study 115: E/C/F/TDF, n = 293 vs. PI+RTV+ F/TDF, n = 140 and Study 121: E/C/F/TDF, n = 291 vs. NNRTI+ F/TDF, n=143) were enrolled and received at least one dose of a study drug. In these four clinical trials, 72 Asian subjects consisting of 50 ART-naïve (E/C/F/TDF, n=23; EFV/F/TDF, n = 10; and ATV+RTV+ F/TDF, n = 17) and 22 ART-experienced, virologically suppressed (Study 115: E/C/F/TDF, n = 7 and PI+RTV+ F/TDF, n=2; and Study 121: E/C/F/TDF and n = 4; NNRTI+ F/TDF, n = 9) were included in this sub-analysis of the E/C/F/TDF data [16].

The baseline demographics and disease characteristics of the ART-naïve (Studies 102 and 103, pooled) and ART-experienced (Study 115 and Study 121, separately) subjects on E/C/F/TDF were as follows: median age 33, 33, and 45 years; male: 83%, 71%, and 100%; mean CD4 count: 374, 548, and 402 cells/mm^3; and median estimated glomerular filtration rate (eGFR) using the Cockcroft-Gault method: 100, 104, and 125 mL/min, respectively (Table 1).

Similar high rates of virological success (HIV-RNA <50 copies/mL, FDA Snapshot Analysis) and comparable immunological outcomes were observed in the ART-naïve and ART-experienced subjects on E/C/F/TDF. In the ART-naïve subjects, the virological success (HIV-1 RNA <50 copies/mL) was 91, 80, and 76% with E/C/F/TDF, EFV/F/TDF, ATV+RTV+ F/TDF, respectively at week 144. The mean CD4+ T cell count (/mm^3) increased from baseline through week 144 (235, E/C/F/TDF; 161, EFV/F/TDF; and 250, ATV+RTV+ F/TDF). In the ART-experienced, virologically suppressed subjects, the virological success (maintenance of HIV-1 RNA <50 copies/mL) of the E/C/F/TDF regimen was 86 and 100% (Studies 115 and 121, respectively) at week 96. The virological success rates for subjects who remained on the PI+RTV+ F/TDF or NNRTI+ F/TDF regimens were 100 and 67%, respectively, both at week 96. The mean CD4+ T cell count increases were similar for E/C/F/TDF in both Studies 115 and 121: 61 and 71 cells/mm^3 compared to -30 and 162 cells/mm^3 for patients who remained on the PI+RTV+ F/TDF and NNRTI+ F/TDF regimens, respectively (Fig. 1).

The overall safety and tolerability of E/C/F/TDF in both ART-naïve and ART-experienced subjects were similar to that of E/C/F/TDF in the overall populations enrolled in the four studies. In the ART naïve subjects, the most common study drug-related adverse events (AEs) with E/C/F/TDF were nausea (n = 4 vs. EFV/F/TDF, n = 0 and ATV+RTV+ F/TDF, n = 5), abnormal dreams (n = 2 vs. 5 and 1, respectively), diarrhea (n = 2 vs. 0 and 3, respectively) and dizziness (n = 1 vs. 2 and 2, respectively). Grade 3AEs occurred in subjects with similar frequency between E/C/F/TDF (17%, n = 4) and EFV/F/TDF (20%, n = 2) while no subjects in the ATV+RTV+ F/TDF treatment arm experienced this Grade. Furthermore, there were no Grade 4 AEs. There were few study drug discontinuations due to AEs in the ART-naïve subjects and the frequency was similar between the treatment arms [E/C/F/TDF, n = 1 due to

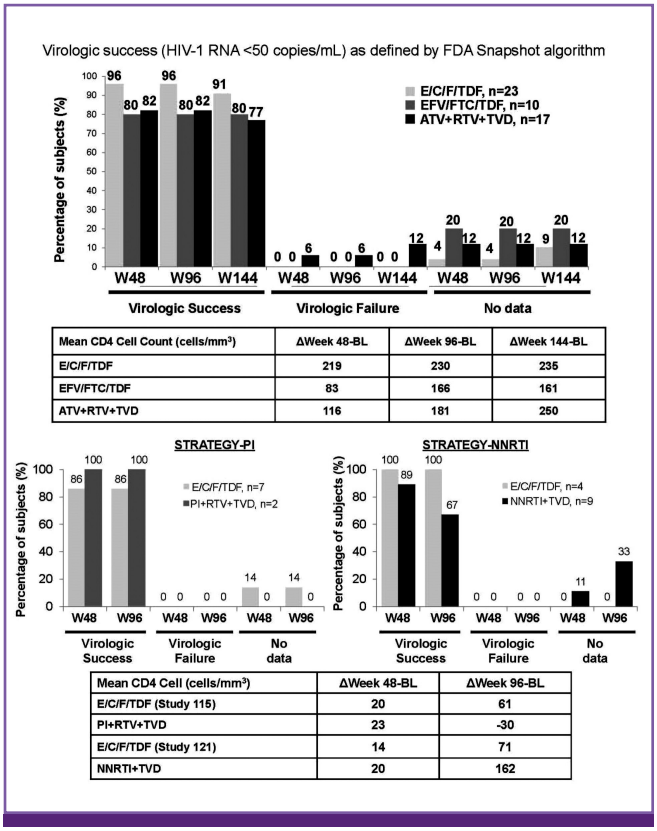

Figure 1. Virological and immunological outcomes studies 102 and 103: Asian subset through week 144.

HIV, human immunodeficiency virus; RNA, ribonucleic acid; FDA, food and drug administration; E, elvitegravir; C, cobicistat; F, emtricitabine; TDF, tenofovir disoproxil fumarate; EFV, efavirenz; FTC, emtricitabine; ATV, atazanavir; RTV, ritonavir; TVD, truvada; PI, protease inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor

lymphoma; EFV/F/TDF, n=1 due to presyncope; and ATV+RTV+ F/TDF, n = 2 due to gastrointestinal disorder consisting of diarrhea (one subject) and nausea, vomiting, and flatulence (one subject, who also had dizziness)]. In the ART-experienced subjects, the most common study drug-related AEs with E/C/F/TDF in Study 115 were, enlarged parotid gland and alopecia (n = 1 each) and in Study 121, increased weight (n = 1) and GFR (n = 1 in male, 47 years old, observed as Grade 1). Only one Grade 3-4 AE occurred in the ART-experienced subjects, which was a subject with a clavicle fracture treated on E/C/F/TDF. There were no subjects on E/C/F/TDF in the ART-experienced studies that discontinued the study drug because of AEs and no subjects in either the ART-naïve or ART-experienced discontinued E/C/F/TDF because of renal AEs. The treatment emergent Grade 3-4 laboratory abnormalities observed with E/C/F/TDF were all Grade 3 (alanine transaminase [ALT], n = 2; aspartate transaminase [AST], n = 1; and hyperuricemia, n = 1) in ART-experienced subjects.

Cobicistat induced a slight increase in serum creatinine (SCr) with a consequent reduction in the eGFR in Phase 1 and 2 clinical trials [17-19]. The changes in SCr are caused by the inhibition of tubular creatinine secretion with no effect on the actual glomerular filtration rate, as measured by the clearance of iohexol [18]. In this sub-analysis in Asian subjects, the median changes from baseline in SCr were similar to that observed in the overall study population on E/C/F/TDF. The median change from baseline in the SCr of the ART-naïve subjects was 0.14 mg/dL with E/C/F/TDF vs. -0.03 mg/dL with EFV/F/TDF and 0.04 mg/dL with ATV+RTV+F/TDF. Furthermore, the values for the ART-experienced subjects were 0.06 mg/dL with E/C/F/TDF vs. -0.18 mg/dL with PI+RTV+F/TDF (Study 115) and 0.05 mg/dL with both E/C/F/TDF and NNRTI+F/TDF (Study 121).

In Asian subjects, the median changes from baseline in the fasting lipid parameters [total cholesterol (TC) and high-density lipoprotein (HDL)] were slight with E/C/F/TDF, which resulted in minimal median changes in the TC:HDL ratio [ART-naïve (0.1) and ART-experienced (Studies 115 and 121, 0.2 and 0.0, respectively)] (Fig. 2)

A limitation of this sub-analysis is the small number of Asian subjects, who accounted for 4 and 3% of the overall population of the participants enrolled in the ART-naïve and ART-experienced studies. This restricted the definitive assessment of the safety and tolerability of E/C/F/TDF in Asian subjects, and may limit generalization of the results.

In these sub-studies of Phase 3 clinical trials of E/C/F/TDF, the Asian subjects with HIV-1 infections who were either initiating E/C/F/TDF therapy or switching to E/C/F/TDF from RTV-boosted PIs or NNRTIs (both combined with F/TDF) demonstrated a high (>90%) efficacy (HIV-1 RNA <50 copies/mL). The safety and tolerability profile of E/C/F/TDF in the Asian subjects was similar to that of E/C/F/TDF in the overall study populations investigated [8, 9, 12, 13]. No new or unique safety concerns were observed in the ART-naïve and ART-experienced Asian subjects on E/C/F/TDF. The AEs leading to study drug discontinuation were uncommon with no renal AEs leading to discontinuation with E/C/F/TDF. Changes in the SCr of Asian subjects on E/C/F/TDF were consistent with those observed in the overall populations enrolled in the ART-naïve and ART-experienced studies. The changes from baseline in SCr observed at week 144 and 96 (ART-naïve and ART-experienced, respectively) were similar to those observed from baseline to week 48, which suggests the initial increase in SCr with E/C/F/TDF was caused by the inhibitory effect of cobicistat on the renal tubular creatinine secretion, which then stabilized [20]. The slight changes in the lipid parameters

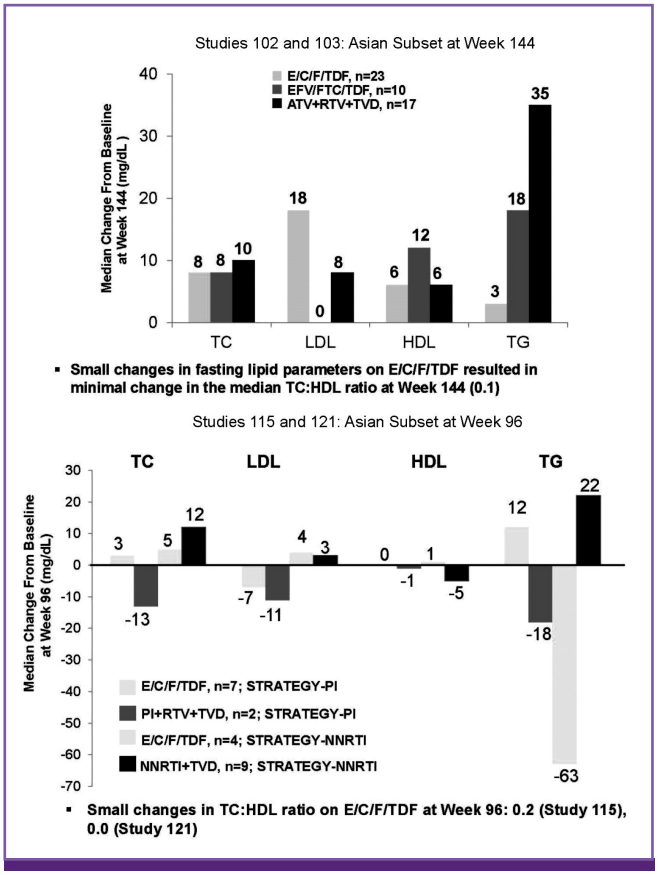

Figure 2. Median change in fasting lipids from baseline.
TC, total cholesterol; LDL, low-density lipoprotein; TG, triglycerides; HDL, high-density lipoprotein.

in Asian subjects on E/C/F/TDF resulted in minimal changes in the TC:HDL ratio and were similar to those in the overall study population. In summary, from this sub-analysis in a small number of Asian subjects, E/C/F/TDF appears to have sustained efficacy and is safe and well-tolerated based on the available data in both the ART-naïve and ART-experienced Asian subjects.

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Conflicts of Interest

No conflicts of interest.

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