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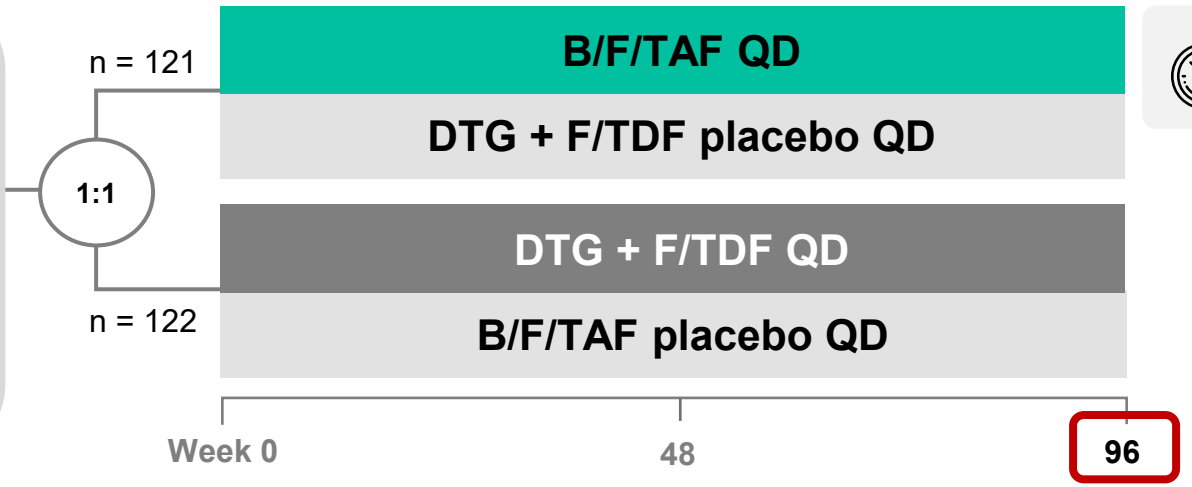
B/F/TAF in Treatment-Naïve Adults With HIV/HBV Co-Infection

Adults with HIV-1 and HBV with no previous HIV-1/HBV treatment

- HIV-1 RNA ≥ 500 c/mL
- HBV DNA ≥ 2,000 IU/mL
- Sensitivity of HIV-1 to FTC and TFV
- $eGFR_{CG}$ ≥ 50 mL/min



May 2018 – Ongoing

In the Primary Analysis at Week 48, B/F/TAF Demonstrated[2]

- Noninferiority to DTG + F/TDF (95% vs. 91%) in achieving HIV-1 RNA < 50 c/mL
- Superiority to DTG + F/TDF (63% vs. 43%) in achieving HBV DNA < 29 IU/mL

Secondary Endpoints at Week 96:

- HIV-1 suppression (HIV-1 RNA <50 copies/mL)
- HBV suppression (HBV DNA <29 IU/mL)
- Change in CD4 cell count/percentage
- ALT normalization
- HBsAg loss/seroconversion
- HBeAg loss/seroconversion

CT.gov: NCT03547908

HBeAg, hepatitis B e antigen; HBsAg, hepatitis B surface antigen; M = F, missing = failure

1. Avihingsanon A, et al. IAS 2023, Late Breaker Poster XXXX; 2. Avihingsanon A, et al. AIDS 2022, Oral OALBX0105

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Baseline Demographic and Clinical Characteristics

Characteristic	B/F/TAF (n = 121)	DTG + F/TDF (n = 122)
Age, years, median (IQR)	31 (27–39)	32 (25–38)
Female at birth, n (%)	9 (7)	2 (2)
Race/ethnicity, n (%)		
Asian	108 (89)	106 (87)
White	10 (8)	9 (7)
Black	2 (2)	6 (5)
Other	1 (1)	1 (1)
HIV-1 RNA, median (IQR) log_{10}, c/mL	4.66 (4.22, 5.12)	4.69 (4.26, 5.04)
CD4 count, cells/mm^3, median (IQR)	245 (127–383)	236 (121–380)
CD4 count < 200 cells/mm^3, n (%)	46 (38)	52 (43)
HBV genotype, n (%)*		
A/D	22 (20)	33 (30)
B/C	84 (75)	74 (68)
HBV DNA ≥ 8 log_{10} IU/mL [median], n (%)	60 (50)	66 (54)
HBeAg positive, n (%)	92 (76)	97 (80)
ALT > ULN, n (%)†	60 (50)	47 (39)

*B/F/TAF, n = 112, DTG + F/TDF, n = 109; †AASLD criteria: 25 U/L (females), 35 U/L (males)
AASLD, American Association for the Study of Liver Diseases; ALT, alanine aminotransferase; HBeAg, hepatitis B e antigen; ULN, upper limit of normal

Avihingsanon A, et al. IAS 2023, Late Breaker Poster XXXX ; Avihingsanon A, et al. CROI 2023, Oral 116; Avihingsanon A, et al. AIDS 2022, Oral OALBX0105

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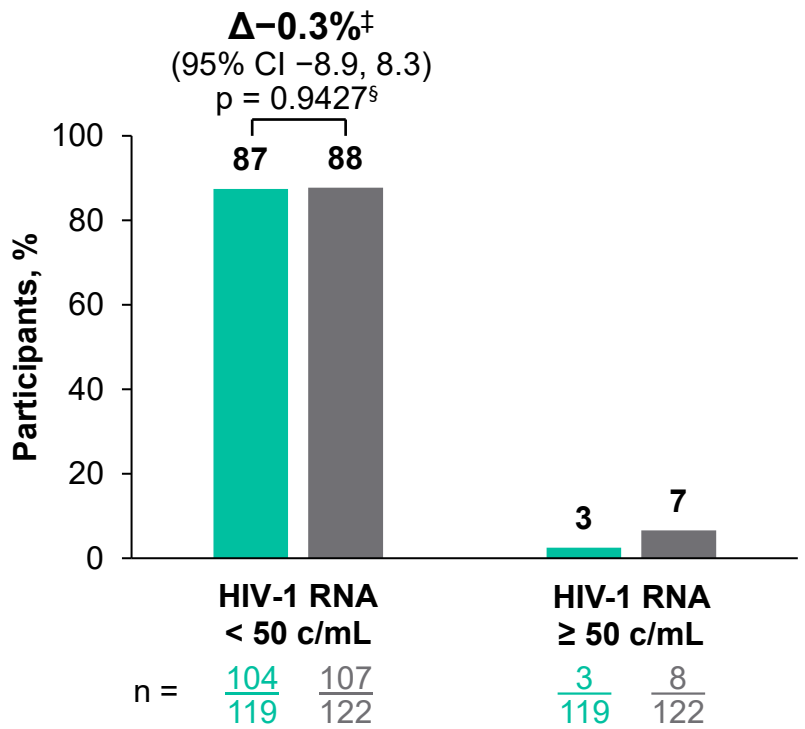
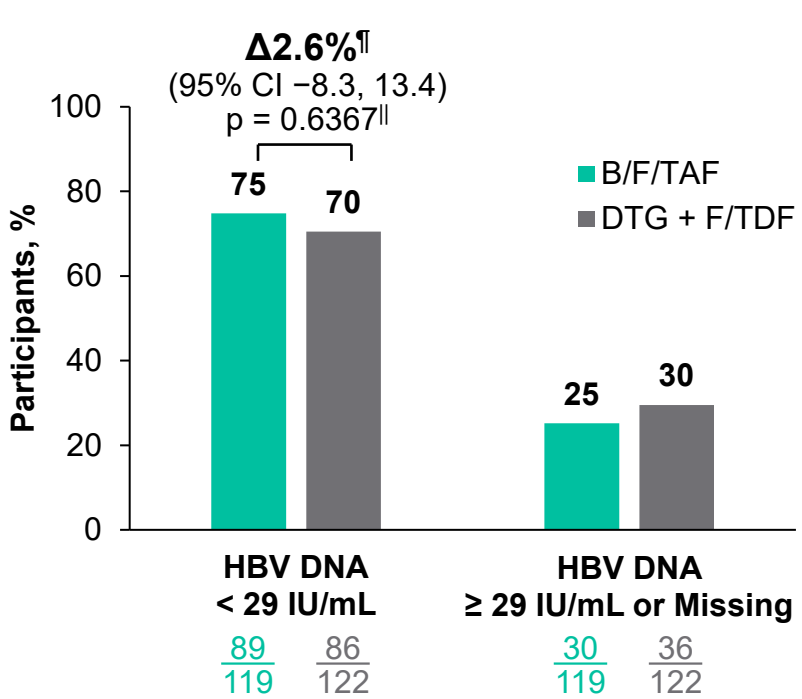
Virologic Outcomes at Week 96

HIV-1 RNA < 50 c/mL
(FDA Snapshot algorithm*)



HBV DNA < 29 IU/mL
(M=F analysis†)



Mean (SD) change from baseline in CD4 cell counts:

B/F/TAF:+261 (+162) cells/μL

DTG + F/TDF:+229 (+174) cells/μL

B/F/TAF and DTG + F/TDF resulted in high rates of HIV-1 RNA and HBV DNA suppression, sustained over 96 weeks in treatment-naïve adults with both HIV-1 and HBV

All p values are nominal. *No data for 12 (10%) and 7 (6%) of participants in B/F/TAF and DTG + F/TDF groups, respectively; †No data for 9 (8%) and 9 (7%) of participants in B/F/TAF and DTG + F/TDF groups, respectively; ‡Based on Mantel-Haenszel (MH) proportions adjusted by baseline HIV-1 RNA stratum (< 100,000 vs. ≥ 100,000 c/mL). §CMH test stratified by baseline HIV-1 RNA stratum. ¶Based on MH proportions adjusted by baseline HBeAg status (positive vs. negative) and HBV DNA category (< 8 vs ≥ 8 log10 IU/mL); ‖CMH test stratified by baseline HBeAg status and baseline HBV DNA category

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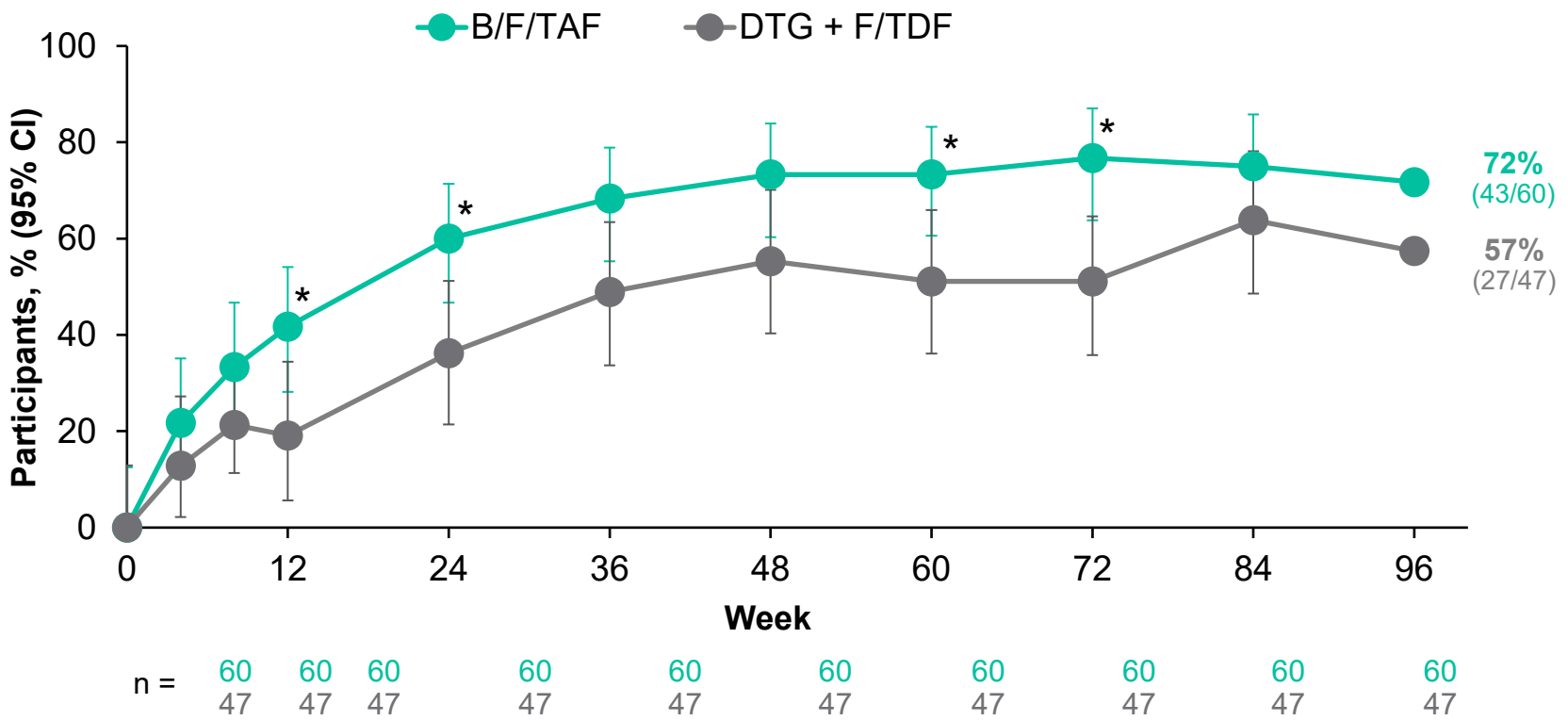
ALT Normalization Through Week 96 (AASLD Criteria)

ALT Normalization in Participants With ALT > ULN at Baseline



Rates of ALT normalization were numerically or statistically significantly higher with B/F/TAF versus DTG + F/TDF over 96 weeks

M=F analysis, full analysis set. AASLD criteria: ULN of 25 U/L for females and 35 U/L for males[8].
*p < 0.05, CMH tests stratified by baseline HBeAg status (positive vs. negative) and baseline HBV DNA (< 8 vs. ≥ 8 log10 IU/mL)

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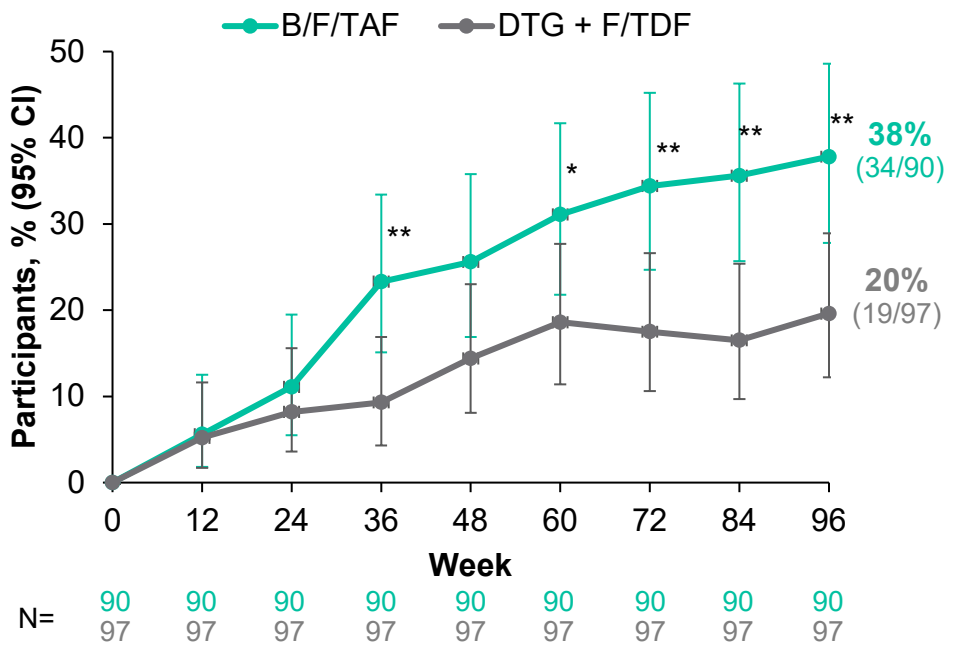
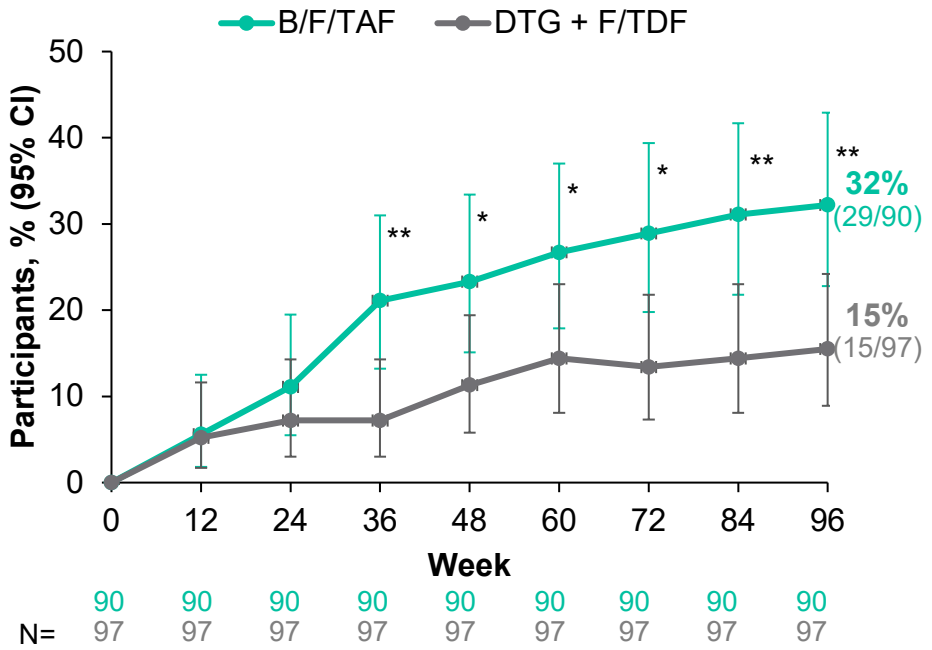
HBeAg Loss and Seroconversion Through Week 96

HBeAg loss



HBeAg seroconversion



- HBeAg positive at baseline, n (%): B/F/TAF: 92 (76) vs DTG + F/TDF: 97 (80)

Rates of HBeAg loss and seroconversion were significantly higher and remained elevated with B/F/TAF versus DTG + F/TDF

M=F analysis in serologically evaluable full analysis set. *p < 0.05, **p < 0.01, CMH tests for HBeAg loss and seroconversion stratified by baseline HBV DNA (< 8 vs. ≥ 8 $\log_{10}$ IU/mL)

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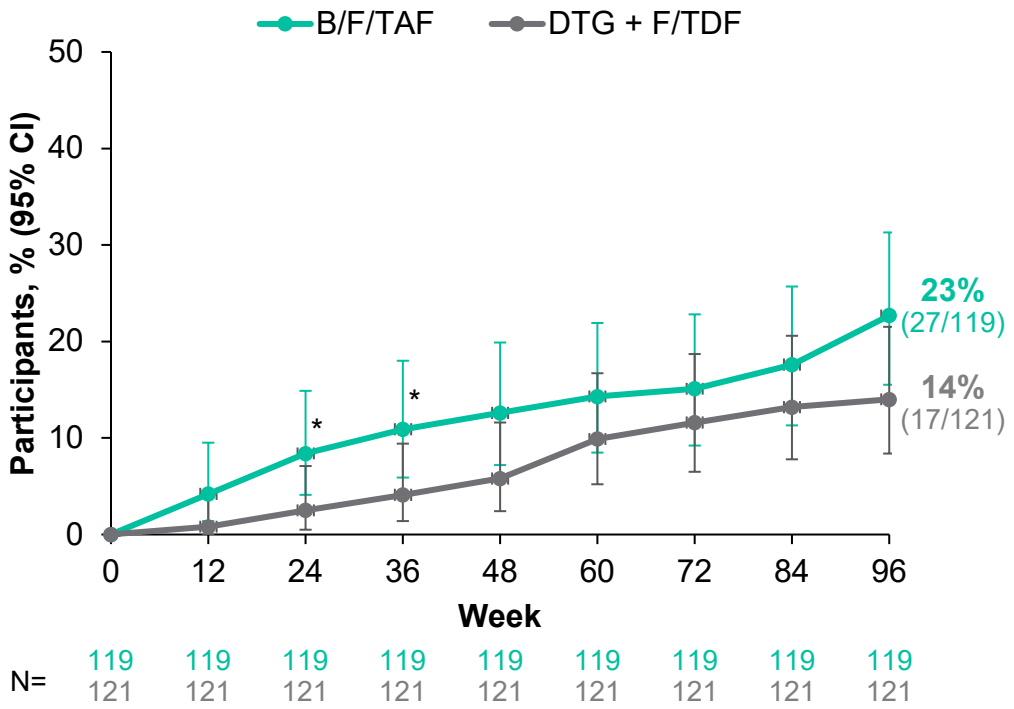
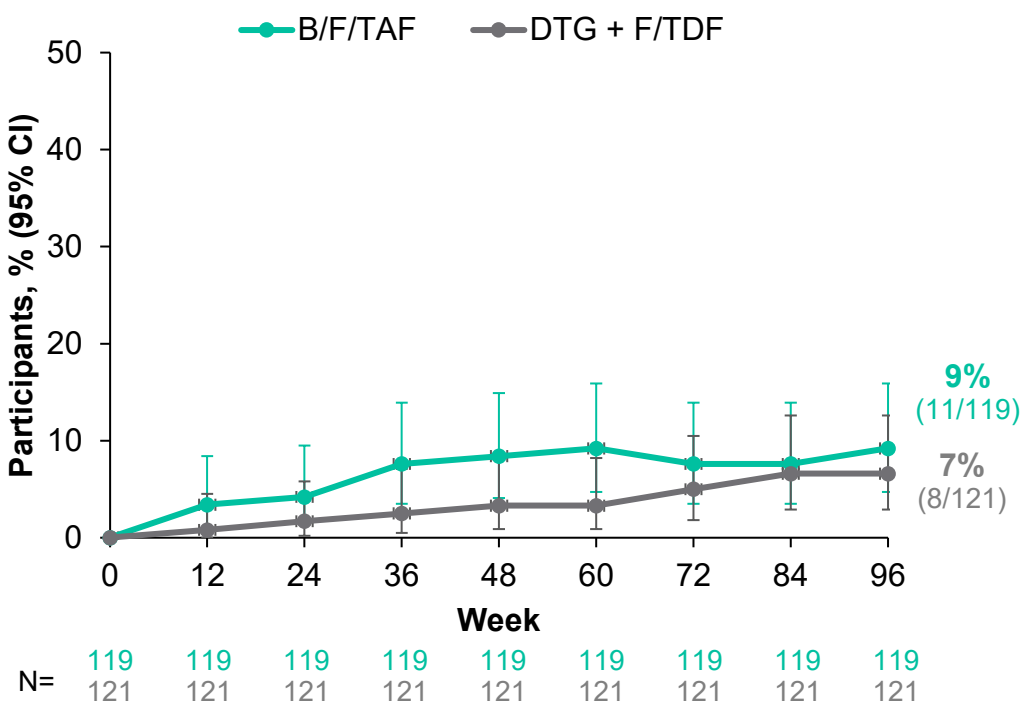
HBsAg Loss and Seroconversion Through Week 96

HBsAg loss



HBsAg seroconversion



Rates of HBsAg loss (functional cure) and seroconversion were numerically or significantly higher with B/F/TAF versus DTG + F/TDF at all timepoints

M=F analysis in serologically evaluable full analysis set. *p < 0.05, CMH tests for HBsAg loss and seroconversion stratified by baseline HBeAg status (positive vs. negative) and baseline HBV DNA (< 8 vs ≥ 8 log10 IU/mL)

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Safety Through Week 96

AEs and laboratory abnormalities, n (%)	B/F/TAF (n = 121)	DTG + F/TDF (n = 122)
Any study drug-related AE	35 (29)	34 (28)
Study drug-related AEs in ≥ 5% of participants in either treatment group		
Weight increased†	10 (8)	12 (10)
ALT increased	2 (2)	8 (7)
Serious AE	17 (14)	16 (13)
Study drug-related serious AE	1 (1)‡	0
AE leading to treatment discontinuation	1 (1)*	0
Death§	2 (2)	1 (< 1)
Any laboratory abnormalities	114 (95)	114 (94)
Any Grade 3 or 4 laboratory abnormalities	45 (38)	39 (32)
Grade 3 or 4 laboratory abnormalities occurring in ≥ 10% in either group		
ALT increased (> 5 × ULN)	26 (22)	16 (13)
AST increased (> 5 × ULN)	16 (13)	14 (12)

Incidences of AEs and laboratory abnormalities were similar between treatment groups

Safety analysis set; multiple AEs were counted only once per participant for the highest severity grade for each preferred term. *Hepatocellular carcinoma on Day 1115 (subsequently died in hospice); †AEs of weight increased or abnormal weight gain; ‡Cryptococcal meningitis attributed to immune reconstitution inflammatory syndrome on Day 32 (resolved on Day 40). §Two participants in the B/F/TAF group died (one due to ischemic heart disease and one due to unknown causes) and one participant in DTG + F/TDF group due to unknown causes

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