GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Rapid Start

This document is in response to your request for information regarding the use of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in rapid antiretroviral therapy (ART) initiation.

Some data may be outside of the US FDA-approved prescribing information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA-approved prescribing information.

The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Summary

Clinical Data: BIC/FTC/TAF in Rapid ART Initiation

Across 11 prospective studies, rapid ART initiation with BIC/FTC/TAF showed high rates of efficacy, with virologic suppression rates ranging from 81% to 100% from 24 weeks to up to approximately 1 year of follow-up.[1-12] In one study that only reported preliminary results up to Week 4, the virologic suppression rate was 52%.[13] In general, there were low rates of Grade ≥3 AEs and discontinuations due to AEs.[1,2,5-12] In a study that compared outcomes between rapid start and non-rapid start of ART, rates of undetectable VL were similar between groups, but participants in the rapid start group had better retention of care than those in the non-rapid start group.[3] An interim analysis of another study showed that participants in the rapid start group had a significantly shorter time to viral suppression from both diagnosis and ART initiation than did participants in the control (non-rapid start) group.[4]

Clinical Data: BIC/FTC/TAF in Rapid ART Initiation

Rapid Initiation With BIC/FTC/TAF vs TDF + 3TC + EFV

Study design and demographics[1]

A multicenter, randomized study in China compared the efficacy and safety of BIC/FTC/TAF vs TDF + 3TC + EFV in rapid ART initiation in MSM newly diagnosed with HIV. Participants who were enrolled to start ART within 14 days of their diagnosis were randomly assigned to BIC/FTC/TAF (n=146) or TDF + 3TC + EFV (n=149). The primary endpoint was the viral suppression rate (VL <50 c/mL) at Week 48 by FDA Snapshot analysis (superiority threshold: lower end of one-sided 95% CI >7%). Secondary endpoints included change from baseline in CD4 cell count, treatment retention, safety, and PROs through Week 48.
Most participants in each treatment group were <35 years of age and of Han ethnicity, with no significant difference between the BIC/FTC/TAF and TDF + 3TC + EFV groups in median age (31 and 32 years, respectively), median baseline VL (4.4 and 4.5 $\log_{10}$ c/mL), median

baseline CD4 cell count (340 and 334 cells/mcL), and median time from diagnosis to treatment (5 days for both groups).

Results

At Week 48, the rate of virologic suppression by FDA Snapshot analysis was 95.9% in the BIC/FTC/TAF group and 79.2% in the TDF + 3TC + EFV group (treatment difference: 16.7%; 95% CI: 9.4–24.2%); 2.1% and 5.4%, respectively, had VL ≥50 c/mL, and 2.1% and 15.4% had no virologic data. Changes from baseline to Week 48 for the BIC/FTC/TAF and TDF + 3TC + EFV groups were as follows: for CD4 count, +223 vs +181 cells/mcL, respectively; for CD4%, +11% vs +7.9%; for CD4/CD8 ratio, +0.36 vs +0.29; increases were significantly greater in the BIC/FTC/TAF group than in the TDF + 3TC + EFV group (each, $P<0.05$).[1]

All participants who remained on treatment and completed the 48-week follow-up in the BIC/FTC/TAF (n=145) and TDF + 3TC + EFV (n=125) groups had good adherence (≥95%) according to pill count.[1]

The rate of AEs was significantly lower in the BIC/FTC/TAF group than in the TDF + 3TC + EFV group (37.7% vs 65.8%, respectively; $P<0.001$), and most AEs were Grade 1 or 2 in severity. The most common AEs (≥10% in either group) were depression, headache, insomnia, and anxiety. Significantly more participants discontinued TDF + 3TC + EFV than BIC/FTC/TAF due to AEs (7.4% vs 0%, respectively; $P=0.001$).[1]

The median (IQR) change from baseline to Week 48 in BMI was 0.9 (0–1.5) kg/m^2 in the BIC/FTC/TAF group and 0 (-0.3 to 0.7) kg/m^2 in the TDF + 3TC + EFV group ($P<0.001$).[1] Changes in BMI from baseline to Week 48 by BMI category are presented in Table 1.

Table 1. BMI Categories at Baseline and Week 48 (Wang et al)[1]

Treatment Group	Participants by Category, %							
	Underweight		Normal		Overweight		Obese	
	Baseline	Wk 48	Baseline	Wk 48	Baseline	Wk 48	Baseline	Wk 48
BIC/FTC/TAF	7.6	4.1	69	64.1	17.9	23.5	5.5	8.3
TDF + 3TC + EFV	8	7.2	67.2	67.2	24	24.8	0.8	0.8

Increases from baseline to Week 48 in TC (BIC/FTC/TAF vs TDF + 3TC + EFV, +0.47 vs +0.02 mmol/L; $P<0.001$) and TG levels (+0.19 vs +0.04 mmol/L; $P=0.29$) were greater in the BIC/FTC/TAF group than in the TDF + 3TC + EFV group. The TC:HDL ratio decreased for both groups (BIC/FTC/TAF vs TDF + 3TC + EFV, −0.38 vs −0.46 mmol/L; $P=0.038$). LDL levels increased from baseline in the BIC/FTC/TAF group but decreased in the TDF + 3TC + EFV group (+0.25 vs −0.14 mmol/L, $P<0.001$).[1]

PROs (depression, anxiety, and stress; HIV treatment symptoms; well-being assessment) improved significantly from baseline to Week 48 in the BIC/FTC/TAF group (9 vs 5; $P=0.002$), but not in the TDF + 3TC + EFV group (10 vs 8; $P=0.853$). The incidences of Grade 3/4 anxiety and depression (according to the Hospital Anxiety and Depression scale) were similar between the BIC/FTC/TAF group (10.5% and 6.8%, respectively) and the TDF + 3TC + EFV group (18% and 11.2%; $P>0.05$ for each); Grade 3/4 insomnia (according to the Pittsburgh Sleep Quality Index) occurred less frequently in the BIC/FTC/TAF group than in the TDF + 3TC + EFV group (61.7% vs 70.1%; $P=0.035$).[1,14]

FAST Study[2]

Study design and demographics

A prospective, multicenter, open-label, single-arm study in France evaluated the safety and efficacy of BIC/FTC/TAF for same-day ART initiation in ART-naive adults who were newly diagnosed with HIV-1 (N=118; Table 2). BIC/FTC/TAF had to be initiated at the first medical appointment after HIV diagnosis and before any laboratory results were available. The primary endpoint was the proportion of participants in the ITT population with a VL <50 c/mL at Week 24 using FDA Snapshot analysis. Secondary endpoints included change from baseline in CD4 cell count, safety, adherence, and feasibility of and satisfaction with immediate ART initiation in the ITT population.

Table 2. FAST Study: Baseline Demographics and Disease Characteristics[2]

Key Demographics and Characteristics	Total Population (N=117)	ITT Population (n=112)
Age, median (IQR), years	37 (29–47)	36 (28–47)
Male, n (%)	104 (88.1)	98 (87.5)
Sexual orientation, MSM/heterosexual, n (%)	83 (70.3)/30 (25.4)	80 (71.4)/27 (24.1)
HIV-1 RNA, median (IQR), log_{10} c/mL	4.8 (4.3–5.4)[a]	4.8 (4.4–5.5)
≥500,000 c/mL, n (%)	21 (18.3)[a]	21 (18.8)
CD4 cell count, median (IQR), mm^3	380 (243–596)[b]	369 (240–570)[c]
<200 cells/mm^3, n (%)	18 (15.8)	18 (16.4)[c]
Delay between HIV diagnosis and ART initiation, median (IQR), days	8 (5–17)	8 (5–17)
Delay between inclusion and ART initiation, same day/1 day, n (%)	117 (99.1)/1 (0.9)	111 (99.1)/1 (0.9)

[a]n=115. [b]n=114. [c]n=110.

Results

In the ITT population, 80.4% (95% CI: 71.8–87.3) and 84.8% (95% CI: 76.8–90.9) of participants had a VL <50 c/mL at Week 24 and Week 48, respectively. The median (IQR) time to suppression was 4 (4–12) weeks. Eleven (9.8%) and 14 (12.5%) participants had protocol-defined virologic failure (two consecutive VLs ≥50 c/mL) at Weeks 24 and 48, respectively; none of these participants had emergent resistance-associated mutations. The median (IQR) changes from baseline to Week 48 in CD4 cell count and CD4/CD8 cell count ratio were +230 (118–360) cells/mL and +0.32 (0.17–0.6), respectively.

BIC/FTC/TAF was well tolerated, and rates of Grade 3 to 4 AEs (15/100 PY) and SAEs were low; none were related to BIC/FTC/TAF. One death by suicide (1/100 PY; unrelated to study drug) occurred. Three Grade 1 AEs led to study drug discontinuation. At Weeks 24 and 48, the median (IQR) changes from baseline in BMI were +0.9 (0.3–1.8) kg/m^2 and +1.2 (0.3–2.1) kg/m^2, respectively.

At Weeks 24 and 48, the self-reported adherence rates were 84.5% and 83.7%, respectively. All participants completed ≥1 of the 4 planned self-administered questionnaires (92.2% of the expected questionnaires were completed) regarding anxiety, acceptability, and general satisfaction. Participants' opinions of same-day treatment initiation with BIC/FTC/TAF were favorable, and participants reported a stress level of 6.3 out of 10. Anxiety levels decreased significantly from a mean level of 52 at baseline to 37 at Week 48 (P<0.001). Overall, mean general/clinical satisfaction and lifestyle/comfort subscale scores increased from baseline to Week 48, ranging from 25.9 to 26.8 (maximum score, 30).

Rapid Initiation vs Initiation >7 Days After Diagnosis[3]

Study design and demographics

An ongoing, prospective, single-center study in the Southern US (Kentucky) compared retention in HIV care and efficacy outcomes between newly diagnosed PWH who initiated ART with BIC/FTC/TAF within 7 business days of their diagnosis (rapid start group) and those who initiated BIC/FTC/TAF >7 days after their diagnosis (non-rapid start group). A total of 107 participants ≥18 years of age were enrolled between July 2021 and August 2022, and follow-up visits occurred at 4 to 8 weeks (Visit 2) and 12 to 16 weeks (Visit 3) after their initial visit, then every 4 to 6 months (Visit ≥4). The primary endpoint was retention in HIV care at 1 year, which was met if a participant had ≥3 clinic visits within the first 12 months of care, attended a clinic visit between 9 and 12 months, and had no care gaps >6 months in duration. Secondary outcomes consisted of virologic suppression rates (HIV RNA <200 c/mL) and CD4 counts. Participants in the rapid start group started ART a median (IQR) of 3 (1–7) days after HIV diagnosis, vs 49 (26–148) days in the non-rapid start group (P<0.001). All participants in the rapid start group and 35 participants (83.3%) in the non-rapid start group initiated BIC/FTC/TAF treatment at the first visit; 1 participant (2.4%) in the non-rapid start group received DTG/3TC. Participants in the non-rapid start group were older, a higher proportion was White, and had a higher CD4 count at baseline than those in the rapid start group (Table 3).

Table 3. Baseline/First Office Visit Demographics and Disease Characteristics (Benidir 2022)[3]

Key Demographics and Characteristics		Rapid Start (n=65)	Non-Rapid Start (n=42)
Age,[a] median (IQR), years		28 (24–36)	35 (28–48)
Female at birth, n (%)		9 (13.8)	9 (21.4)
Race,[b] n (%)	White	28 (43.8)	27 (64.3)
	African American	24 (37.5)	13 (31)
	American Indian/Alaskan Native	0	1 (2.4)
	Other/ ≥2 races	12 (18.8)	1 (2.4)
Hispanic ethnicity, n (%)		11 (17.7)	2 (4.8)
Medical history of HCV/HBV, n (%)		6 (9.2)/1 (1.5)	10 (25)/3 (7.5)
Social factors associated with transmission, n (%)	MSM[c]	41 (64.1)	15 (39.5)
	Heterosexual	18 (28.1)	16 (43.2)
	IV drug use	13 (20.3)	13 (34.2)
	Bisexual	4 (6.2)	4 (10.8)
HIV VL, median (IQR), c/mL		50,150 (15,200–268,000)	47,900 (9030–398,250)
CD4 cell count,[d] median (IQR), cells/mm^3		351 (183–514)	476 (336–716)

[a]P=0.005. [b]P=0.024. [c]P=0.027. [d]P=0.003.

Retention and efficacy results

The retention rate at Visit 4 was significantly higher and the median times to Visits 2 and 3 were significantly shorter in the rapid start group than in the non-rapid start group. The proportion of participants who achieved undetectable VLs did not differ significantly between groups at any visit. Median CD4 cell counts were significantly higher at baseline and at all study visits through Visit 4 in the non-rapid start group than in the rapid start group. No safety outcomes were reported.

Table 4. Rates of Retention in Care and Undetectable VL by Visit (Benidir 2022)[3]

Outcome		Rapid Start	Non-Rapid Start	*P*-Value
Visit 1	Undetectable VL, n/N (%)	2/64 (3.1)	3/43 (7.1)	≥0.05
Visit 2	Retention in HIV care, n/N (%)	50/55 (90.9)	31/41 (75.6)	0.05
	Time to visit, median (IQR), days	43.5 (35.3–58.3)	63 (48.5–122.5)	0.001
	Undetectable VL, n/N (%)	31/49 (63.3)	23/29 (79.3)	≥0.05
Visit 3	Retention in HIV care, n/N (%)	24/38 (63.2)	16/32 (50)	0.387
	Time to visit, median (IQR), days	118 (99.5–141.8)	238.5 (156.8–250)	0.002
	Undetectable VL, n/N (%)	19/25 (76)	12/16 (75)	≥0.05
Visit 4	Retention in HIV care, n/N (%)	9/16 (56.3)	2/22 (9.1)	0.003
	Time to visit, median (IQR), days	192 (185–238)	243.5 (180.2–306.8)	0.885
	Undetectable VL, n/N (%)	9/9 (100)	3/4 (75)	≥0.05
Visit 5	Undetectable VL, n/N (%)	3/3 (100)	1/1 (100)	≥0.05

RoCHaCHa Study[4]

Study design and demographics

A prospective, open-label, single-center study evaluated BIC/FTC/TAF for rapid ART initiation (same day) in adult participants who were newly diagnosed with HIV-1 and were ART naive (N=45). Interim results were reported for participants who had been in care for ≥3 months as of May 2021. Enrolled participants were aged ≥18 years, had been diagnosed with HIV-1 ≤21 days prior to study enrollment, had CrCl >30 mL/min, and weighed >35 kg. Participants in the rapid start group (n=34) received BIC/FTC/TAF once daily and were followed through 48 weeks. Outcomes were compared with those of participants who received standard-of-care therapy (non-rapid start; historical control, n=24) between January 2016 and August 2017. The primary endpoints were the median times from diagnosis to viral suppression with a VL <200 c/mL and <50 c/mL and from ART initiation to viral suppression. Thirty-four participants had >3 months of data, and 21 participants completed 48 weeks of the study.

Table 5. RoCHaCHa Study: Baseline Demographics and Disease Characteristics[4]

Key Demographics and Characteristics	Rapid Start (n=34)	Control (n=24)
Age at diagnosis, mean (SD), years	32.2 (9.8)	36.3 (13.3)
Male at birth, n (%)	33 (97.1)	19 (79.2)
Race, White/Black, n (%)	18 (52.9)/14 (41.2)	11 (45.8)/10 (41.7)
Non-Hispanic ethnicity, n (%)	22 (64.7)	20 (83.3)
Homosexual, n (%)	20 (58.8)	11 (45.8)
HIV-1 VL prior to ART initiation, median (IQR), log_{10} c/mL	4.5 (3.7–5)	4.7 (4.3–5.1)
≥100,000 c/mL prior to ART initiation, n (%)	8 (23.5)	9 (37.5)
IV drug use ever, n (%)	6 (17.6)	3 (12.5)
CD4 cell count prior to ART initiation, median (IQR), cells/mm^3	462 (338–644)	447 (291.75–647.5)
<200 cells/mm^3 prior to ART initiation, n (%)	1 (2.9)	3 (12.5)

Results

Twenty of 21 participants (95%) who received rapid start BIC/FTC/TAF were virologically suppressed at Week 48. At the time of the interim analysis, no participants had modifications made to their BIC/FTC/TAF regimen due to resistance or virologic failure. Participants in the rapid start group had a significantly shorter time to virologic suppression and higher treatment retention rates than those in the control group. Safety data were not reported from this study.

Table 6. RoCHaCHa Study: Retention in Care and Efficacy Outcomes[4]

	Rapid Start (n=34)	Control (n=24)
Time from diagnosis to clinic presentation, median (IQR),[a] days	1 (0–4)	9.5 (6–22.25)
Time from clinic presentation to ART, median (IQR),[a] days	0	35.5 (28–57)
Time from diagnosis to VL <200 c/mL, median (IQR),[a] days	16 (11–31)[b]	94 (83.75–199)
Time from ART initiation to VL <200 c/mL, median (IQR),[a] days	14 (7–28)[b]	34 (29.75–62.75)
Time from ART initiation to VL <50 c/mL, median (IQR),[a] days	16 (11–31)[b]	187.5 (113–340.8)
Retention in care at Week 12,[c] n/N (%)	29/34 (88.2)	12/24 (50)
Retention in care at Week 24,[c] n/N (%)	25/31 (80.6)	9/24 (38)
Retention in care at Week 48,[c] n/N (%)	19/22 (86.4)	9/24 (38)
Pharmacy adherence through Week 48,[d] n (median %)	21 (91)	9 (67)

[a]$P<0.001$. [b]n=33; viral suppression data were unknown for 1 participant. [c]$P<0.05$. [d]$P\geq0.05$.

Additional Clinical Data on BIC/FTC/TAF in Rapid ART Initiation

Table 7. Summary of Additional Studies of Rapid Start BIC/FTC/TAF[5-13]

Study Design	Study Population/Treatment	Efficacy Results	Safety Results

Prospective, single-arm, multicenter cohort study in Taiwan[5]	225 ART-naive PWH who initiated BIC/FTC/TAF within 24 hours of confirmed HIV diagnosis	• Wk 48 (ITT analysis):
		  • VL <50 c/mL: 76.3% (167/219)
		  • VL <200 c/mL: 89.5% (196/219)
		• Wk 48 (LOCF):
		  • VL <50 c/mL: 81.3% (183/225)
		  • VL <200 c/mL: 96.4% (217/225)
			• No BIC/FTC/TAF-related severe AEs reported
			• 2 discontinuations (0.9%) due to skin rash

BIC-NOW study: open-label, single-arm, multicenter, phase 4 study in Spain[6]	208 PWH; test-and-treat model of BIC/FTC/TAF initiation; all participants initiated within 1 wk of diagnosis
	• 98.6% (205/208) initiated on same day of diagnosis
		• VL <50 c/mL at Wk 48:
		  • ITT analysis: 175/208 (84.1%)
		  • PP analysis: 175/178 (98.3%)
		• CD4 cell counts and CD4/CD8 ratio improved from baseline (*P*=0.0001 for both)
			• No Grade 3–4 AEs or discontinuations due to AEs
			• Significant increases from baseline to Wk 48 in weight, BMI, TC, HDL, and TG and significant decreases in ALT, GGT, and CrCl (*P*≤0.035 for each)

SIMPLIFIED study: prospective, single-center, phase 4, mobile outreach clinical study in Spain[7]	101 vulnerable PWH (ie, reported drug use, were homeless, were undocumented immigrants); “Test, treat, and retain” approach
	  • 100% of eligible participants had same-day BIC/FTC/TAF initiation
		• Wk 48 (of the 64.4% who remained in care):
		  • VL <50 c/mL: 96.9%
		  • VL ≥50 c/mL: 3.1%
		• CD4 cell counts increased numerically from baseline to Week 48 (*P*-value not provided)
		• Incomplete adherence was reported in 57.3%, and 10.1% had treatment interruptions >20 days. No cases of virologic failure were reported
			• 69 participants (68.3%) reported ≥1 AE; most AEs (95.3%) were mild in intensity
			• 2 AEs (1%) were deemed related to BIC/FTC/TAF
			• 5 SAEs were reported: hospitalization, n=3; life-threatening, n=1; death, n=1
			• No AE led to permanent discontinuation

Prospective, single-arm, single-center, proof-of-concept study in Spain[13]	100 newly diagnosed PWH who initiated BIC/FTC/TAF within the first wk of HIV diagnosis, prior to lab test results • 64% initiated the day of diagnosis	Preliminary results reported up to Wk 4: • VL <50 c/mL: 52% • Ineligible for other rapid ART initiation regimens (primary endpoint): 72%	Safety data were not reported
BIC-PHI clinical trial: single-arm, multicenter study in Spain[8]	64 participants with confirmed PHI (<3 mo post-infection) who initiated rapid ART with BIC/FTC/TAF; 78% initiated within 72 h of diagnosis; 100% within 24 h of first specialist visit	VL <50 c/mL at Wk 48 (primary endpoint): • ITT analysis: 52/64 (81%) • On-treatment analysis: 52/56 (93%; 95% CI: 83–98%)	• ≥1 AE reported in 72% of participants (Grade 3–4, 3%) • No AEs led to discontinuation • 91% of AEs unrelated to BIC/FTC/TAF • 4 SAEs, all unrelated to treatment

Study Design	Study Population/Treatment	Efficacy Results	Safety Results
BIFAST study: open-label, non-randomized, single-center, phase 4 study in Spain[9]	59 participants referred to HIV clinic and offered same-day ART with BIC/FTC/TAF • n=39 with lab data; n=20 without lab data	Efficacy at Wk 24: • ITT analysis: 50/59 (84.4%) • PP analysis: 50/54 (92.6%)	• 1 BIC/FTC/TAF discontinuation due to suspected tuberculosis infection • No other safety data reported
BFTAFDU Study: prospective, open-label, single-arm, multicenter pilot study in Greece[10]	36 PWHID who were ARV-naive or had discontinued ART for >3 months and initiated ART within 7 days (median time from diagnosis, 0 d) with BIC/FTC/TAF and PNS; 122 historical controls (median time from diagnosis to treatment initiation, 141.5 days)	VL <40 c/mL among participants: • Wk 24 (±30 days): 20/22 (90.9%) • Wk 48 (±30 days): 8/8 (100%) VL <40 c/mL among historical controls: • Wk 24, 40%	• 4 participants with Grade 3–4 SAEs unrelated to treatment • No AEs related to treatment led to discontinuation
Open-label, two-arm, phase 3b, multicenter study in the UK[11]	36 PWH with confirmed HIV-1 diagnosis <14 days before BIC/FTC/TAF or DRV/c/FTC/TAF initiation	• Mean decrease in HIV RNA from ARV initiation to Week 12 of 3.1 $\log_{10}$ c/mL in the BIC/FTC/TAF group and 2.6 $\log_{10}$ c/mL in the DRV/c/FTC/TAF group (P<0.001). • Week 12 VL <50 c/mL (ITT analysis): 84% (16/19) in the BIC/FTC/TAF group and 35% (6/17) in the DRV/c/FTC/TAF group (P<0.05) • Week 48 VL <50 c/mL (ITT analysis): 74% (14/19) in the BIC/FTC/TAF group and 65% (11/17) in the DRV/c/FTC/TAF group	• 22 participants had DRAEs (BIC/FTC/TAF, n=13; DRV/c/FTC/TAF, n=9) • No Grade 3 or 4 AEs were reported • 8 participants with ≥1 Grade 3 laboratory abnormality (BIC/FTC/TAF, n=3; DRV/c/FTC/TAF, n=5); none related to study drugs
Rainbow study: prospective, single-arm, single-center, phase 4 study in Italy[12]	30 ART-naive adults with advanced HIV-1 (CD4 cell count <200 cells/mcL and/or the presence of an AIDS-defining event) who initiated BIC/FTC/TAF ≤7 days after HIV diagnosis	Wk 48 (ITT population): • 90% with VL <50 c/mL • 3 clinical or unconfirmed virological failures • 83% with CD4 count >200 cells/mcL • CD4 cell counts and CD4/CD8 ratio significantly improved from baseline (P<0.001 for both)	• 6 SAEs (n=3); 2 cases (6.6%) of IRIS • No treatment discontinuations for safety • Grade 3 (37%) and Grade 4 (3%) lab abnormalities were unrelated to treatment • Increases from baseline in weight, BMI, and Cr (each, P<0.001) • eGFR decreased (P<0.001)

Abbreviations: DRAE=drug-related adverse event; DRV/c/FTC/TAF=darunavir/cobicistat/emtricitabine/tenofovir alafenamide; GGT=γ-glutamyl transferase; IRIS=immune reconstitution inflammatory syndrome; lab=laboratory; PHI=primary HIV infection; PNS=peer navigation support; PP=per protocol; PWHID=people with HIV who inject drugs; TN=treatment naive.

References

1. Wang R, Sun L, Wang X, et al. Rapid Initiation of Antiretroviral Therapy with Coformulated Bictegravir, Emtricitabine, Tenofovir Alafenamide Versus Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate in HIV-positive Men Who Have Sex with Men in China: Week 48 Results of the Multicenter, Randomized Clinical Trial. *Clin Infect Dis.* 2024:ciae012.
2. Bachelard A, Isernia V, Charpentier C, et al. Same-day initiation of bictegravir/emtricitabine/tenofovir alafenamide: Week 48 results of the FAST study-IMEA 055. *J Antimicrob Chemother.* 2023;78(3):769-778.
3. Benidir B, Sanchez LP, Salunkhe V, Gootee S, Ali T, Arnold F. Impact of rapid initiation of antiretroviral therapy on retention in care in the Southern United States [Poster]. Paper presented at: ID Week; October 19-23, 2022; Washington, DC.
4. Zuppelli A, Scutaru J, Danforth A, et al. Interim Analysis of Real-World Community-Based HIV Rapid Start Antiretroviral with BFTAF Versus Conventional HIV Antiretroviral Therapy Start The RoCHaCHa Study a Pilot Study [Poster #880]. Paper presented at: IDWeek 2021; 29 September - 03 October, 2021; San Diego, CA.
5. Huang Y-C, Sun H-Y, Lu P-L, et al. Multicentre, prospective cohort study of same-day initiation of antiretroviral therapy with BIC/FTC/TAF among antiretroviral-naïve people with HIV [Poster 152]. Paper presented at: HIV Glasgow; November 10-13, 2024; Glasgow, UK.
6. Hidalgo-Tenorio C, Sequera S, Collado A, et al. Bictegravir/Emtricitavine/Tenofovir alafenamide as first line treatment in naive HIV patients in a rapid-initiation model of care: BIC NOW clinical trial [Poster]. Paper presented at: 19th European AIDS Conference (EACS); October 18-21, 2023; Warsaw, Poland.
7. Ryan P, Cuevas G, Torres P, et al. Simplified Access and Retention Model for Vulnerable People With HIV: SIMPLIFIED Study Results. [Poster #693]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); March 9-12, 2025; San Francisco.
8. Ambrosioni J, De-Lazzari E, Suanzes P, et al. Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) for the treatment of primary HIV infection (PHI): the DIC-PHI clinical trial. Paper presented at: AIDS 2024; July 22-26, 2024; Munich, Germany.
9. Al-Hayani AWM, Carrillo I, Cabello A, et al. Starting antiretroviral therapy (ART) at the first HIV-specialist appointment with or without baseline laboratory data with BIC/FTC/TAF (the BIFAST study) [Poster]. Paper presented at: AIDS 2022; 29 July-2 August, 2022; Montreal, Quebec, Canada.
10. Psichogiou M, Protopapas K, Roussos S, et al. Rapid ART initiation with BIC/FTC/TAF in HIV-positive people who inject drugs (naive or re-linking to care) : a pilot study of an integrated care model (BFT AFDU study) [Poster 2886]. Paper presented at: AIDS 2024, the 25th International AIDS Conference; July 22-26, 2024; Munich, Germany, and virtually.
11. Whitlock G, Fidler S, Clarke A, et al. A randomised control trial of BIC/F/TAF vs DRV/c/F/TAF in context of HIV test-and-treat, BicTnT. *HIV Res Clin Pract.* 2024;25(1):2400453. https://www.ncbi.nlm.nih.gov/pubmed/39244669
12. Camici M, Gagliardini R, Lanini S, et al. Rapid ART initiation with bictegravir/emtricitabine/tenofovir alafenamide in individuals presenting with advanced HIV disease (Rainbow study). *Int J Antimicrob Agents.* 2024;63(1):107049.
13. Ugarte A, de la Mora L, Chivite I, et al. Rapid initiation of antiretroviral therapy (ART) with bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in a tertiary hospital in Barcelona, Spain: a prospective clinical trial [Poster P076]. Paper presented at: HIV Glasgow 23-26 October, 2022; Glasgow, UK.
14. Wang R, Sun L, Wang X, et al. Rapid Initiation of Antiretroviral Therapy with Coformulated Bictegravir, Emtricitabine, Tenofovir Alafenamide Versus Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate in HIV-positive Men Who Have Sex with Men in China: Week 48 Results of the Multicenter, Randomized Clinical Trial [Supplement]. *Clin Infect Dis.* 2024:ciae012.

Abbreviations

3TC=lamivudine
AE=adverse event
ART=antiretroviral therapy
BIC=bictegravir
c/mL=copies/mL
CD=cluster of differentiation
DTG=dolutegravir
EFV=efavirenz
FTC=emtricitabine
MSM=men who have sex with men
PRO=patient-reported outcome
PWH=people with HIV
PY=person-years
SAE=serious adverse event
TAF=tenofovir alafenamide
TC=total cholesterol
TDF=tenofovir disoproxil fumarate
TG=triglycerides
VL=viral load

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Biktarvy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

Data Privacy

The Medical Information service at Gilead Sciences may collect, store, and use your personal information to provide a response to your medical request. We may share your information with other Gilead Sciences colleagues to ensure that your request is addressed appropriately. If you report an adverse event or concern about the quality of a Gilead or Kite product, we will need to use the information you have given us in order to meet our regulatory requirements in relation to the safety of our medicines.

It may be necessary for us to share your information with Gilead's affiliates, business partners, service providers, and regulatory authorities located in countries besides your own. Gilead Sciences has implemented measures to protect the personal information you provide. Please see the Gilead Privacy Statement (www.gilead.com/privacy-statements) for more information about how Gilead handles your personal information and your rights. If you have any further questions about the use of your personal information, please contact privacy@gilead.com.