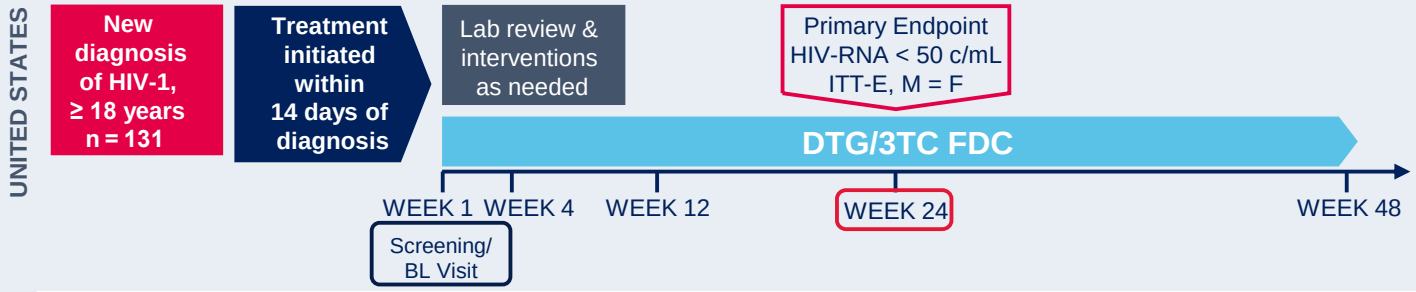
Use of *Dovato* in 'Test and Treat' Strategy: The STAT Study

The STAT study (ClinicalTrials.gov, NCT03945981) is a phase 3b, multicenter, open-label, single-arm, pilot study assessing the feasibility, efficacy, and safety of using *Dovato* (dolutegravir/lamivudine [DTG/3TC]) as a first-line regimen in a 'test-and-treat' model of care in the United States[1]

Study Design[1,2]

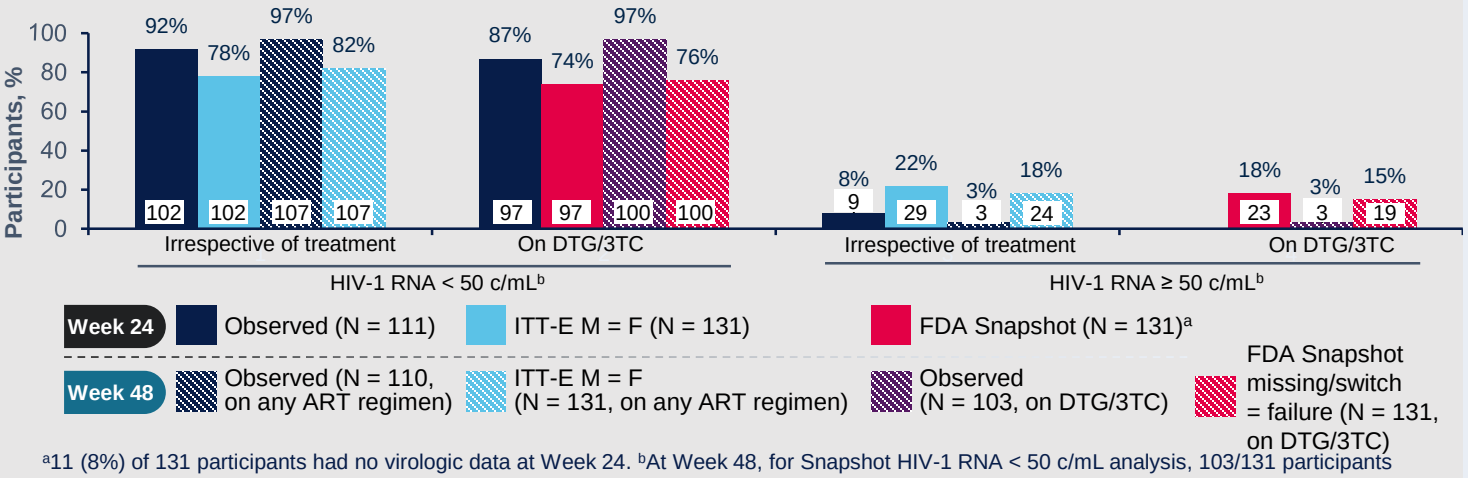


Participants could be included with: No VL cap, unknown resistance, adherence, Hep B and CrCl status

Participants were evaluated for possible treatment modification due to: Chronic HBV co-infection, baseline transmitted resistance, CrCl < 30 mL/min/1.73m^2, protocol-defined virologic failure, new pregnancy, AEs of toxicities (if deemed necessary by the investigator or if toxicities met protocol stopping criteria)

- 131 participants were enrolled in the study across 16 sites (median age was 31 years, 47% African American, 29% Hispanic/Latino)
- Through Week 48, DTG/3TC treatment was adjusted in 10 participants; 18 (14%) participants discontinued study before Week 48
  - 2 participants met the inclusion criteria for 2 positive HIV tests and enrolled in the study, but later they were found to be HIV negative and withdrew from study

Results of Efficacy Analyses: Virologic Outcomes at Week 24 and Week 48[1,2]



[a]11 (8%) of 131 participants had no virologic data at Week 24. [b]At Week 48, for Snapshot HIV-1 RNA < 50 c/mL analysis, 103/131 participants were on DTG/3TC; for Snapshot HIV-1 RNA ≥ 50 c/mL analysis, 19/131 participants were on any ART regimen. 12 (9%) of 131 participants had no virologic data at Week 48.

Summary of Virologic Outcomes at Week 24 and 48[1,2]

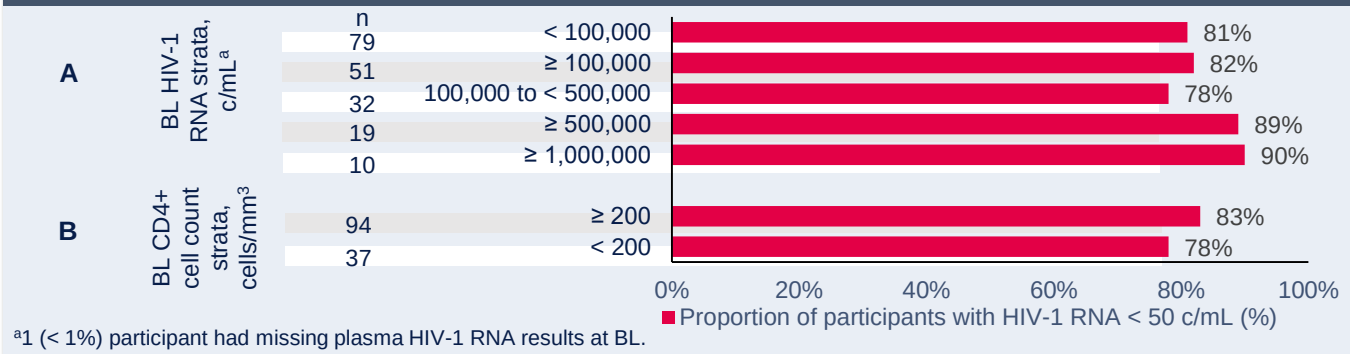
	Week 24 DTG/3TC, n/N (%)	Week 48 DTG/3TC, n/N (%)
ITT-E missing = failure analysis		
HIV-1 RNA < 50 c/mL	**102/131 (78)**	**107/131 (82)**
HIV-1 RNA ≥ 50 c/mL	**29/131 (22)**	**24/131 (18)**
Data in window and HIV-1 RNA ≥ 50 c/mL	9/131 (7)	3/131 (2)
On study but missing data in window	5/131 (4)[a]	3/131 (2)[d]
Discontinued study due to lost to follow-up/withdrew consent	12/131 (9)[b]	14/131 (11)[e]
Discontinued study for other reasons	3/131 (2)[c]	4/131 (3)[f]
Observed analysis		
HIV-1 RNA < 50 c/mL	102/111 (92)	107/110 (97)
On DTG/3TC	97/111 (87)	100/107 (93)
On modified ART	5/111 (5)	7/107 (7)

Table continued on Page 2

	Week 24 DTG/3TC, n/N (%)	Week 48 DTG/3TC, n/N (%)
FDA Snapshot analysis		
HIV-1 RNA < 50 c/mL	**97/131 (74)**	**100/131 (76)**
HIV-1 RNA ≥ 50 c/mL	**23/131 (18)**	**19/131 (15)**
Data in window and HIV-1 RNA ≥ 50 c/mL	9/131 (7)	3/131 (2)
Discontinued for lack of efficacy	0	0
Discontinued study for other reason and HIV-1 RNA ≥ 50 c/mL	6/131 (5)	6/131 (5)
Change in ART	8/131 (6)	10/131 (8)
No virologic data	**11/131 (8)**	**12/131 (9)**

[a]3 participants missed HIV-1 RNA assessment at Week 24 due to COVID-19. [b]7 due to lost to follow-up; 5 withdrew consent (3 relocations, 1 incarceration, 1 no sub-reason). [c]3 due to physician decision (2 HIV negative, 1 did not show up to several scheduled appointments). [d]1 participant missed HIV-1 RNA assessment at Week 48 due to COVID-19. [e]8 due to lost to follow-up; 6 withdrew consent (3 relocations, 2 incarcerations, 1 no sub-reason). [f]All due to physician decision (2 HIV negative, 2 did not show up to several scheduled appointments).

Proportion of Participants With Plasma HIV-1 RNA < 50 copies/mL at Week 48 by BL (A) HIV-1 RNA and (B) CD4+ Cell Count (ITT-E M = F Analysis)[2]



[a]1 (< 1%) participant had missing plasma HIV-1 RNA results at BL.

View the full MI letter for information on participants who switched from DTG/3TC at any point by Week 48.[1,2] Full MI letter

AEs Reported Under Treatment With DTG/3TC[2]

Treatment with DTG/3TC (N = 131) resulted in low rates of grade 2-5 drug-related AEs (2%) and serious AEs (2%).

Any AE

76%

Any SAE

2%[b]

Drug-related AEs

8%

Grade 2-5 drug-related AEs

2%[c]

AEs leading to discontinuation of DTG/3TC

< 1%[a]

Psychiatric disorders[d]

18%

AEs occurring in ≥ 7% of participants

9%

Headache

8%

Diarrhea

7%

Depression

7%

Nausea

[a]1 AE leading to discontinuation of DTG/3TC occurred (rash); The event resolved. [b]2 SAEs occurred (cellulitis, streptococcal bacteremia). No fatal SAEs occurred. [c]All AEs were grade 2. [d]All psychiatric AEs were grade 1 or 2. AEs were coded using MedDRA v23.1.

For more information MI Letter | Prescribing Information | CLICK FOR ViiV US Medical Portal

The Prescribing Information, including the boxed warning(s) can also be accessed at Our HIV Medicines.

Some information contained in this response may be outside the approved Prescribing Information. This response is not intended to offer recommendations for administering this product in a manner inconsistent with its approved labeling. In order for ViiV Healthcare to monitor the safety of our products, we encourage healthcare professionals to report adverse events or suspected overdoses to the company at 877–844–8872. Please consult the Prescribing Information. This response was developed according to the principles of evidence-based medicine and, therefore, references may not be all-inclusive.

Abbreviations: 3TC = lamivudine; ABC = abacavir; AE = adverse event; ART = antiretroviral therapy; BIC = bictegravir; BL = baseline; c = copies; Cobi = cobicistat; CrCl = creatinine clearance; DRV = darunavir; DTG = dolutegravir; FDC = fixed dose combination; FTC = lamivudine; HBV = hepatitis B virus; Hep B = hepatitis B; HIV = human immunodeficiency virus; ITT-E = intent-to-treat-exposed; MedDRA = Medical Dictionary for Regulatory Activities; M = F = missing = failure; NA= not available; RNA = ribonucleic acid; RPV = rilpivirine; TAF = tenofovir alafenamide; TDF = tenofovir disoproxil fumarate; VL = viral load.

References: 1. Rolle et al. ACTHIV 2020; Chicago, Illinois. Poster; **2.** Rolle et al. IAS 2021; Virtual Event. E-Poster.