NEW FINDINGS

Two head-to-head trials comparing the safety and efficacy of DOVATO vs BIKTARVY

Dovato
dolutegravir 50 mg/
lamivudine 300 mg tablets

NEW HEAD-TO-HEAD DATA

The DYAD and PASO DOBLE studies are Phase 4, randomized, open-label, clinical trials of DOVATO head-to-head vs BIKTARVY[1,2]

BIKTARVY is a registered trademark of Gilead Sciences, Inc. See US Prescribing Information for further information.

INDICATION

DOVATO is indicated as a complete regimen to treat HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known resistance to any component of DOVATO.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: PATIENTS CO-INFECTED WITH HEPATITIS B VIRUS (HBV) AND HIV-1: EMERGENCE OF LAMIVUDINE-RESISTANT HBV AND EXACERBATIONS OF HBV

All patients with HIV-1 should be tested for the presence of HBV prior to or when initiating DOVATO. Emergence of lamivudine-resistant HBV variants associated with lamivudine-containing antiretroviral regimens has been reported. If DOVATO is used in patients co-infected with HIV-1 and HBV, additional treatment should be considered for appropriate treatment of chronic HBV; otherwise, consider an alternative regimen.

Severe acute exacerbations of HBV have been reported in patients who are co-infected with HIV-1 and HBV and have discontinued lamivudine, a component of DOVATO. Closely monitor hepatic function in these patients and, if appropriate, initiate anti-HBV treatment.

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information, including Boxed Warning, for DOVATO.

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ViiV Healthcare

Breadth of data: DOVATO achieves and maintains viral suppression with fewer medicines[1-6]

Pivotal Phase 3 trials

gemini 1 | gemini 2

3 YEARS

DTG + 3TC (n=716) vs
DTG + TDF/FTC (n=717)
in treatment-naïve participants[4,6]

TANGO

4 YEARS

DOVATO (n=369) vs
TAF-containing regimens (n=372)
in virologically suppressed participants[3,7]

Phase 4 head-to-head trials

DYAD

1 YEAR

DOVATO (n=149) vs
BIKTARVY (n=73) in virologically
suppressed participants[1]

PASO DOBLE

1 YEAR

DOVATO (n=277) vs
BIKTARVY (n=276) in virologically
suppressed participants[2]

View GEMINI and TANGO studies at dovatohcp.com

3TC=lamivudine; DTG=dolutegravir; FTC=emtricitabine; TAF=tenofovir alafenamide; TDF=tenofovir disoproxil fumarate.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- Do not use DOVATO in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
- Do not use DOVATO in patients receiving dofetilide

Two head-to-head studies comparing the efficacy and safety of DOVATO vs BIKTARVY[1,2]

DYAD

Phase 4, single-center, open-label RCT in the US

HIV-1 positive adults virologically suppressed on BIKTARVY[1]

See DYAD >

PASO DOBLE

Phase 4, multicenter, open-label RCT in Spain

HIV-1 positive adults virologically suppressed on an ART regimen containing >1 daily pill or containing a COBI booster, EFV, or TDF[2]

See PASO DOBLE >

Across both studies

Primary endpoint: noninferior efficacy

- Proportion of participants with HIV-1 RNA ≥50 copies/mL at Week 48

ART=antiretroviral therapy; COBI=cobicistat; EFV=efavirenz; RCT=randomized controlled trial; TDF=tenofovir disoproxil fumarate.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
- Discontinue DOVATO immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

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ViiV Healthcare

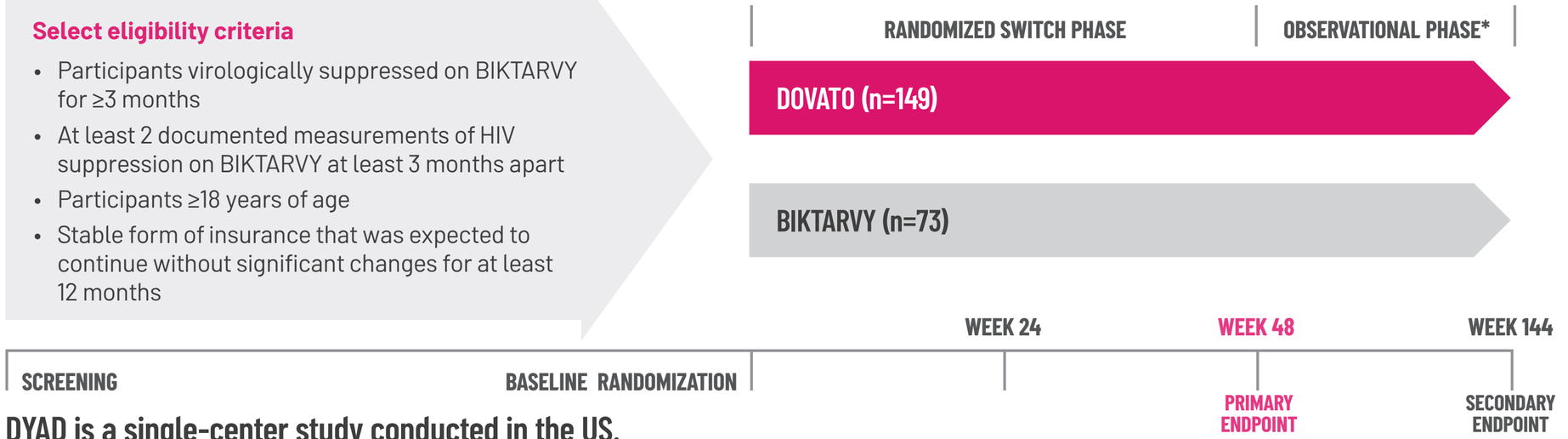
DYAD: A head-to-head, randomized (2:1), open-label, noninferiority trial of DOVATO vs BIKTARVY

DYAD

222 adult participants who started on BIKTARVY either switched to DOVATO or continued BIKTARVY[1,8]

Select eligibility criteria

- Participants virologically suppressed on BIKTARVY for ≥3 months
- At least 2 documented measurements of HIV suppression on BIKTARVY at least 3 months apart
- Participants ≥18 years of age
- Stable form of insurance that was expected to continue without significant changes for at least 12 months



Select exclusion criteria

- HBV infection or acute need for HCV therapy
- History of prior viral failure
- Suspected or documented INSTI resistance
- Major NRTI resistance

Primary endpoint

- Proportion of participants with HIV-1 RNA ≥50 copies/mL at Week 48 using the FDA Snapshot algorithm (ITT-E) and a 6% noninferiority margin

Secondary endpoints

- Proportion of participants with plasma HIV-1 RNA <50 copies/mL at Weeks 48, 96, and 144 in the ITT-E population
- Mean change in weight from baseline at Week 48, compared using 2-sample t-tests

DYAD is a single-center study conducted in the US.

*Observational phase follows participants after they exit DYAD in the real world and collects 96- and 144-week efficacy and safety data recorded in the electronic medical record.

HBV=hepatitis B virus; HCV=hepatitis C virus; INSTI=integrase strand transfer inhibitor; ITT-E=intent-to-treat-exposed; NRTI=nucleoside reverse transcriptase inhibitor.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Hepatotoxicity:

- Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
- Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of DOVATO. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn
- Monitoring for hepatotoxicity is recommended

Please see additional Important Safety Information throughout.

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ViiV Healthcare

On average, participants were on ART for ~10 years and took 3 prior ART regimens[1]

DYAD

BASELINE CHARACTERISTICS	DOVATO (n=149)	BIKTARVY (n=73)
Age, median (range), years	**49** (24–73)	**51** (20–73)
≥50, n (%)	**74** (50%)	**44** (60%)
Female, n (%)	**24** (16%)	**12** (16%)
Race, n (%)		
Caucasian	**102** (68%)	**54** (74%)
Black	**44** (30%)	**18** (25%)
Asian	**1** (1%)	**0** (0%)
Ethnicity, n (%)		
Hispanic or Latino	**43** (29%)	**22** (30%)
Weight, median (range), kg	**90.4** (53.1–171.9)	**88.5** (59.1–123.5)
CD4⁺ T-cell count, median (range), cells/mm³	**720.5** (214–1479)	**734.5** (151–1573)
Duration of ART prior to Day 1, median (range), years	**12** (1–32)	**9.5** (1–27)
Number of prior ART regimens	**3** (1–9)	**3** (1–10)
Participants with unknown genotype, n (%)	**89** (60%)	**36** (49%)

The study population had a median age of **~50 years, 16% female,** and **~30% non-white PLHIV**

60% of participants in the DOVATO arm had unknown resistance history

For insurance coverage in the DOVATO arm, 89% had private insurance, 3% were on Medicaid, and 8% were on Medicare.

PLHIV=people living with HIV.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Lactic Acidosis and Severe Hepatomegaly With Steatosis:

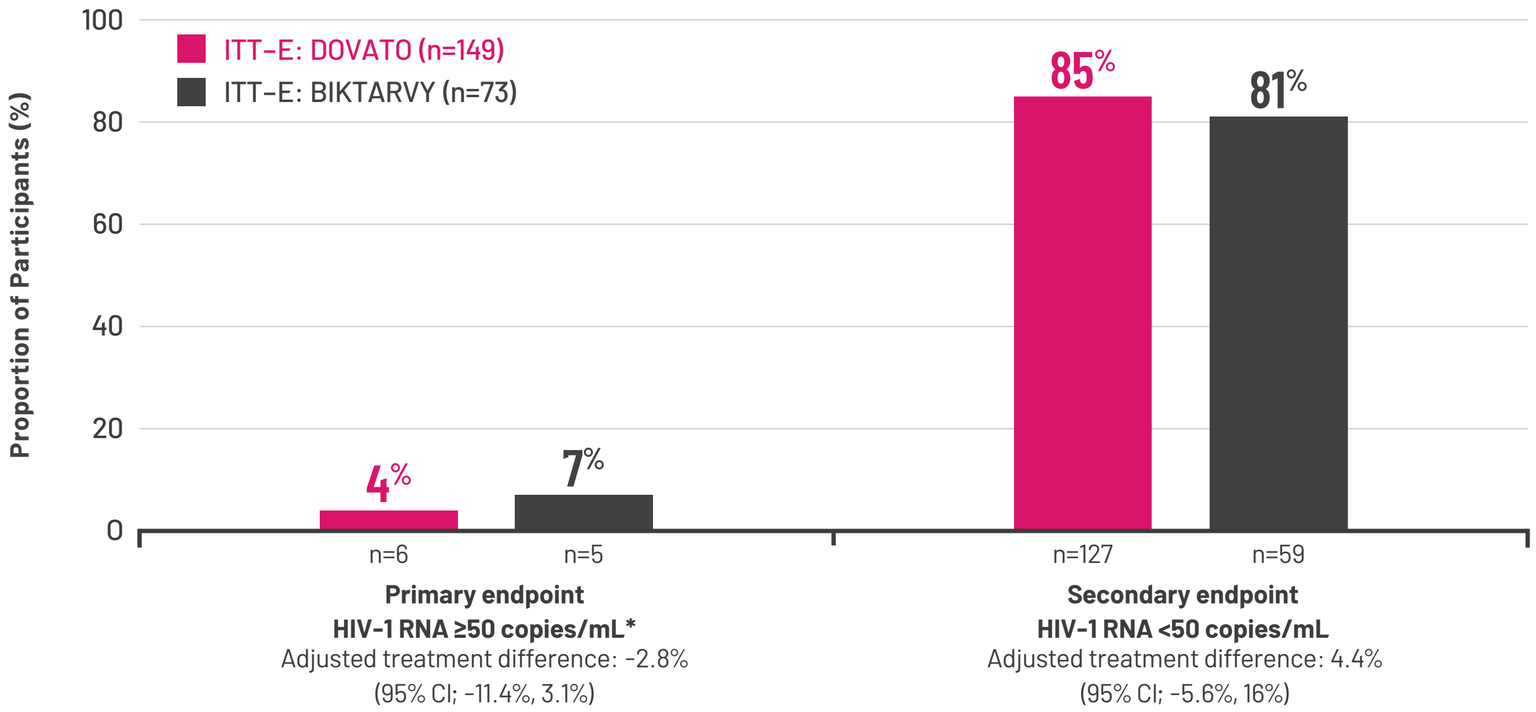
Fatal cases have been reported with the use of nucleoside analogs, including lamivudine. Discontinue DOVATO if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of DOVATO and other drugs may occur (see Contraindications and Drug interactions).

DOVATO was noninferior to BIKTARVY at 48 weeks,* with fewer medicines

DYAD

Virologic outcomes at Week 48 by FDA Snapshot analysis[1]



Noninferiority criteria were not specified for the HIV-1 RNA <50 copies/mL endpoint.

There was no virologic data for 16 (11%) participants in the DOVATO arm and 9 (12%) participants in the BIKTARVY arm.

*Noninferiority analysis with a 6% margin using the Farrington-Manning Score Test.
CI=confidence interval.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of DOVATO.

Adverse reactions

The most common adverse reactions (incidence ≥2%, all grades) with DOVATO were headache (3%), nausea (2%), diarrhea (2%), insomnia (2%), fatigue (2%), and anxiety (2%).

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ViiV Healthcare

A high barrier to resistance and no cases of INSTI resistance for DOVATO through Week 48

DYAD

Cases of CVW with treatment-emergent resistance[1*†]

	DOVATO (n=149)	BIKTARVY (n=73)
Confirmed virologic withdrawal (cumulative)	12 (8.1%)	6 (8.2%)
Participants with treatment-emergent resistance[†‡]	1	1
Cases of treatment-emergent resistance by type		
NRTI resistance	1	1
INSTI resistance	**0**	**1**

0 CASES

of INSTI resistance were reported in the DOVATO arm through Week 48 vs 1 case in the BIKTARVY arm

*Confirmed virologic withdrawal was defined as 2 consecutive HIV-1 RNA values ≥50 copies/mL. Only participants meeting CVW criteria were assessed for treatment-emergent resistance.

†One non-CVW DOVATO participant developed SVF at Week 4 with an HIV-1 RNA of 148 copies/mL but did not return for confirmatory testing. At Week 12, HIV-1 RNA was 87 copies/mL and a genotype was inadvertently collected at this initial episode of unconfirmed viremia. Genotypic testing demonstrated K65R, M184V, T215S, and K219E. The participant was discontinued from the trial at Week 12, at which time they had an HIV-1 RNA <50 copies/mL on DOVATO. The participant was suppressed when they discontinued DOVATO and transitioned to a DTG-based regimen (DTG + DRV/c). A baseline genotypic test demonstrated no NRTI or INSTI resistance.

‡One participant in the DOVATO arm demonstrated TAMs and M184V resistance but no integrase resistance. This participant switched to a DTG-based regimen (DTG +DRV/c) and was suppressed at the time of the switch. In the BIKTARVY arm, 1 participant demonstrated M184M/I and integrase resistance (G140G/S). The participant in the BIKTARVY arm was suppressed when they discontinued from the study, and they remained on BIKTARVY.

CVW=confirmed virologic withdrawal; DRV/c=darunavir/cobicistat; SVF=suspected virologic failure; TAM=thymidine analogue mutation.

IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions

- Consult full Prescribing Information for DOVATO for more information on potentially significant drug interactions
- DOVATO is a complete regimen. Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that induce or inhibit CYP3A or UGT1A1 may affect the plasma concentrations of dolutegravir
- Administer DOVATO 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, DOVATO and supplements containing calcium or iron can be taken with food

Adverse events through Week 48[1]

DYAD

AEs	DOVATO (n=149), n (%)	BIKTARVY (n=73), n (%)
Participants reporting drug-related AEs, all Grades	**31** (21%)	**2** (3%)
Participants reporting any drug-related AEs, Grades 2-5	**14** (9%)	**1** (1%)
Drug-related AEs (occurring in ≥2%)		
Nausea	**7** (5%)	**0** (0%)
Fatigue	**6** (4%)	**0** (0%)
Diarrhea	**5** (3%)	**0** (0%)
Headache	**5** (3%)	**0** (0%)
Insomnia	**5** (3%)	**0** (0%)
Worsening depression	**3** (2%)	**0** (0%)
Dizziness	**3** (2%)	**0** (0%)
AEs leading to withdrawal	**6** (4%)	**1** (1%)
Drug-related AEs leading to withdrawal*	**6** (4%)	**0** (0%)
Serious adverse events†	**12** (8%)	**4** (5%)

The single-switch, open-label nature of this study should be considered when assessing the number of drug-related AEs and withdrawals for DOVATO

*Drug-related AEs leading to withdrawal included neuropsychiatric complaints (4), pancreatitis (1), and nausea (1).

†Included 1 drug-related SAE in the DOVATO arm (pancreatitis). All other SAEs were unrelated to the drug, and no fatal SAEs were observed.

AE=adverse event; SAE=serious adverse event.

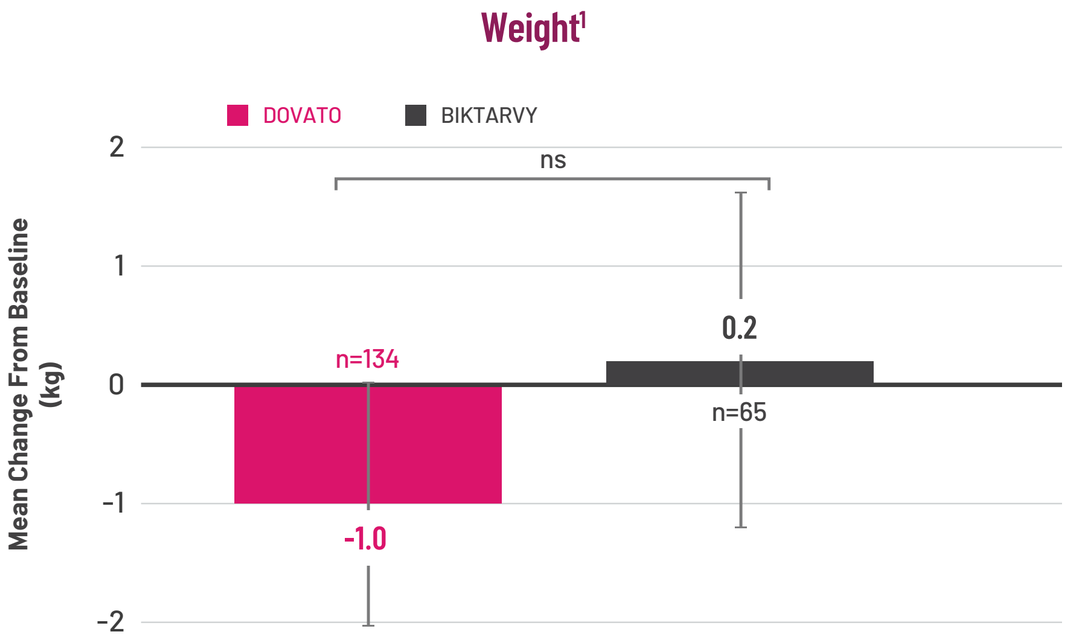
IMPORTANT SAFETY INFORMATION (cont'd)

Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of DOVATO during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established
- **Lactation:** Potential risks of breastfeeding include HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant
- **Renal Impairment:** DOVATO is not recommended for patients with creatinine clearance <30 mL/min. Patients with a sustained creatinine clearance between 30 and 49 mL/min should be monitored for hematologic toxicities, which may require a dosage adjustment of lamivudine as an individual component
- **Hepatic Impairment:** DOVATO is not recommended in patients with severe hepatic impairment (Child-Pugh Score C)

Mean change in weight at Week 48

DYAD



There was no statistically significant difference between arms in mean change in weight from baseline

Clinical significance of these data is unknown.
ns=not significant.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- Do not use DOVATO in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
- Do not use DOVATO in patients receiving dofetilide

The largest head-to-head clinical trial of DOVATO vs BIKTARVY to date*

PASO DOBLE

A Phase 4, randomized (1:1), open-label, noninferiority trial of DOVATO vs BIKTARVY[2,9]

Select inclusion criteria
- Virologically suppressed ≥24 weeks
- On current regimen containing >1 daily pill, COBI booster, EFV, or TDF
- No evidence of previous viral failure
- No known or suspected resistance to study drugs

DOVATO (n=277)

BIKTARVY (n=276)

Stratification by use of TAF-containing regimen at baseline and sex at birth

SCREENING	BASELINE RANDOMIZATION	WEEK 48	WEEK 96

Select exclusion criteria
- Previously treated with DTG or BIC
- Chronic hepatitis B

Primary endpoint
- Proportion of participants with plasma HIV-1 RNA ≥50 copies/mL at Week 48 in the ITT-E population (FDA Snapshot, 4% noninferiority margin)

Secondary endpoints
- Proportion of participants with plasma HIV-1 RNA <50 copies/mL at Weeks 48 and 96 in the ITT-E population (FDA Snapshot, -8% noninferiority margin)
- Absolute weight change at Week 48 and Week 96
- Proportion of participants with weight change >5% from baseline at Week 48 and Week 96

PASO DOBLE is a multicenter study conducted in Spain.

All participants had no prior exposure to DTG or BIC. 72% of participants were on an ART regimen without TAF prior to randomization

*The other clinical trials comparing DOVATO vs BIKTARVY are DYAD (N=222) and RUMBA (N=134).[1,10]
BIC=bictegravir; EVG/c=elvitegravir/cobicistat.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

Hypersensitivity Reactions:
- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
- Discontinue DOVATO immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

PASO DOBLE studied >500 participants who had on average ~11 years on ART[2]

PASO DOBLE

BASELINE CHARACTERISTICS	DOVATO (n=277)	BIKTARVY (n=276)
Age, years, median (IQR)	**50** (41-57)	**51** (39-58)
Sex, n (%)		
Female	**74** (26.7%)	**73** (26.4%)
Ethnicity, n (%)		
Caucasian	**201** (72.6%)	**201** (72.8%)
Latin	**66** (23.8%)	**67** (24.3%)
Black	**4** (1.4%)	**5** (1.8%)
CD4⁺ <350 cells/mm³, n (%)	**26** (9.4%)	**24** (8.7%)
Years on ART, years, median (IQR)	**11.7** (7.2-19.3)	**11.1** (7.0-19.2)
Duration of prior ART regimen, months, median (IQR)	**66.2** (43.5-97.0)	**62.8** (41.1-88.7)
Presence of TAF in previous ART, n (%)	**77** (27.8%)	**78** (28.3%)
Presence of TDF in previous ART, n (%)	**92** (33.2%)	**10 3** (37.3%)
Weight at baseline, kg, median (IQR)[11]	**72.8** (63.4, 83.3)	**72.8** (63.0, 81.8)
BMI, kg/m², median (IQR)	**25.1** (22.3-28.5)	**24.8** (22.2-28.2)
Overweight/obese (BMI >25 kg/m²), n (%)	**143** (51.8%)	**134** (48.6%)

Across both arms, participants were, on average, **~50 years of age** and on ART for **~11 years**

BMI=body mass index; IQR=interquartile range.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

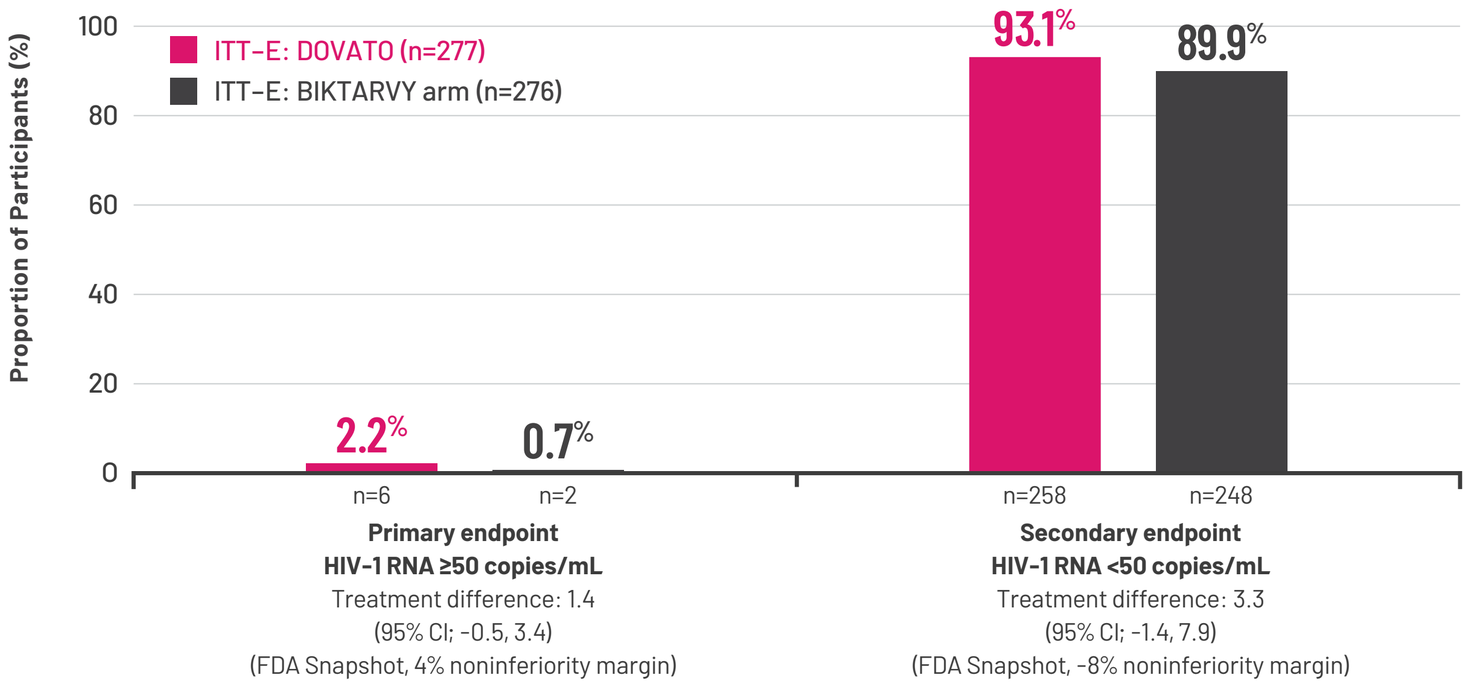
Hepatotoxicity:

- Hepatic adverse events have been reported, including cases of hepatic toxicity (elevated serum liver biochemistries, hepatitis, and acute liver failure), in patients receiving a dolutegravir-containing regimen without pre-existing hepatic disease or other identifiable risk factors
- Patients with underlying hepatitis B or C or marked elevations in transaminases prior to treatment may be at increased risk for worsening or development of transaminase elevations with use of DOVATO. In some cases, the elevations in transaminases were consistent with immune reconstitution syndrome or hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn
- Monitoring for hepatotoxicity is recommended

DOVATO was noninferior to BIKTARVY at 48 weeks

PASO DOBLE

Snapshot outcomes at Week 48 in ITT-E population[2]



At Week 48, 13 (4.7%) participants on DOVATO and 26 (9.4%) participants on BIKTARVY had no virologic data.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Lactic Acidosis and Severe Hepatomegaly With Steatosis:

Fatal cases have been reported with the use of nucleoside analogs, including lamivudine. Discontinue DOVATO if clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity develop, including hepatomegaly and steatosis in the absence of marked transaminase elevations.

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of DOVATO and other drugs may occur (see Contraindications and Drug interactions).

DOVATO had a high barrier to resistance similar to BIKTARVY at Week 48

PASO DOBLE

Cases of CVF with treatment-emergent resistance through Week 48[2*†]

	DOVATO (n=277)	BIKTARVY (n=276)
Confirmed virologic failure	**0**	**1**
Emergent resistance	0	0

0 CASES

of CVF and emergent resistance in the DOVATO arm

*Only participants meeting CVF criteria were assessed for treatment-emergent resistance.
†Confirmed virologic failure was defined as HIV-1 RNA ≥50 copies/mL followed by a second consecutive HIV-1 RNA assessment ≥200 copies/mL.
CVF=confirmed virologic failure.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of DOVATO.

Adverse reactions

The most common adverse reactions (incidence ≥2%, all grades) with DOVATO were headache (3%), nausea (2%), diarrhea (2%), insomnia (2%), fatigue (2%), and anxiety (2%).

Adverse events through Week 48[2]

PASO DOBLE

AEs	DOVATO (n=277), n (%)	BIKTARVY (n=276), n (%)
Any AE*	**207** (74.7%)	**216** (78.3%)
Grade 3-4 AEs	**3** (1.1%)	**10** (3.6%)
Serious AEs	**12** (4.3%)	**13** (4.7%)
Drug-related AEs	**19** (6.9%)	**27** (9.8%)
AEs leading to withdrawal	**1** (<1%)	**2** (<1%)

The most common drug-related AEs were not reported by the study investigators.

*Most common AEs (>10% in either arm) per system organ class for DOVATO and BIKTARVY arms were, respectively: infections (36.8% and 45.3%), musculoskeletal disorders (19.5% and 18.5%), gastrointestinal disorders (17.3% and 10.5%), metabolism disorders (13.7% and 9.4%), and psychiatric disorders (9.7% and 13.4%).

See Important Safety Information on previous page for most common adverse reactions.

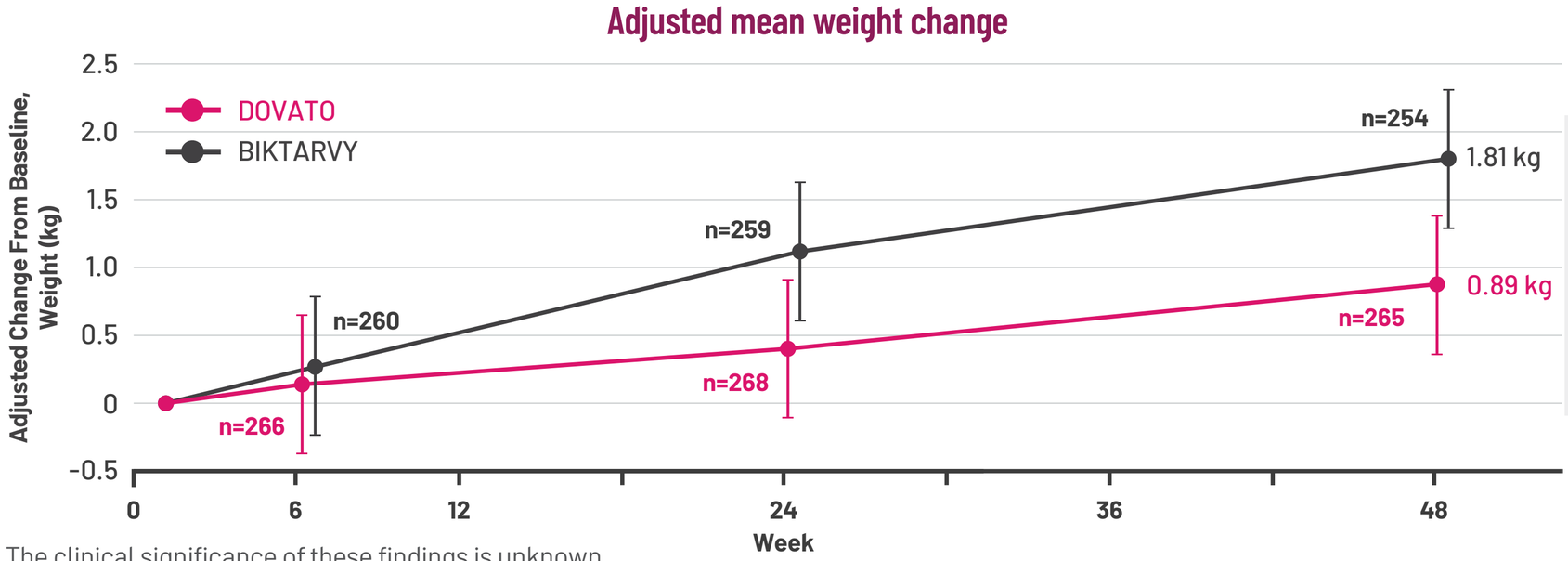
IMPORTANT SAFETY INFORMATION (cont'd)

Drug interactions

- Consult full Prescribing Information for DOVATO for more information on potentially significant drug interactions
- DOVATO is a complete regimen. Coadministration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended
- Drugs that induce or inhibit CYP3A or UGT1A1 may affect the plasma concentrations of dolutegravir
- Administer DOVATO 2 hours before or 6 hours after taking polyvalent cation-containing antacids or laxatives, sucralfate, oral supplements containing iron or calcium, or buffered medications. Alternatively, DOVATO and supplements containing calcium or iron can be taken with food

At Week 48, DOVATO participants experienced statistically significantly less weight gain vs those on BIKTARVY[2]

PASO DOBLE



Mean Adjusted Treatment Difference

Week 48
0.92 kg
(95% CI; 0.17, 1.66; *P*=0.016)

At Week 48, participants in the BIKTARVY arm gained more weight than DOVATO participants

Adjusted by baseline value, sex, presence of TAF in previous ART, age, and ethnicity.

The clinical significance of these findings is unknown.

Change in weight from baseline at Week 48 for DOVATO was consistent with the TANGO study.[11]

Data from Week 48 was a prespecified secondary endpoint. Data from Weeks 6 and 24 were not specified endpoints.[9]

IMPORTANT SAFETY INFORMATION (cont'd)

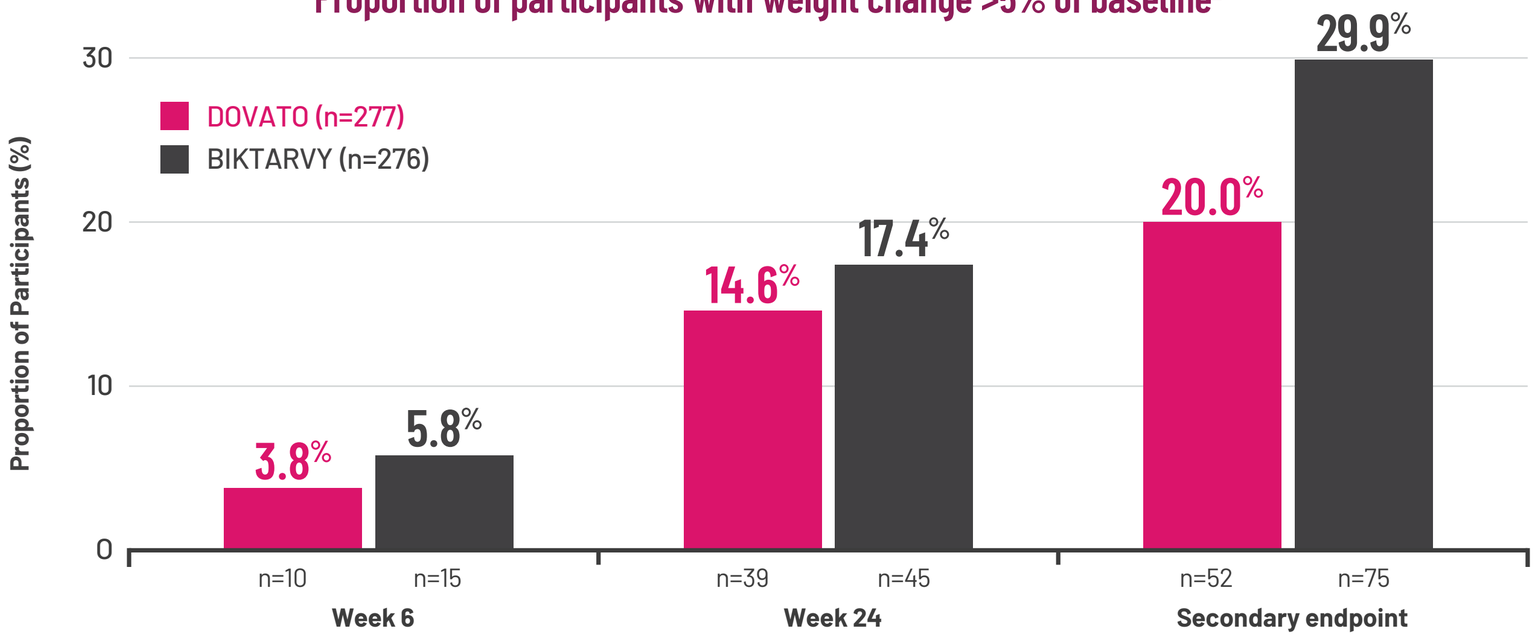
Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of DOVATO during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established
- **Lactation:** Potential risks of breastfeeding include HIV-1 transmission, developing viral resistance in HIV-positive infants, and adverse reactions in a breastfed infant
- **Renal Impairment:** DOVATO is not recommended for patients with creatinine clearance <30 mL/min. Patients with a sustained creatinine clearance between 30 and 49 mL/min should be monitored for hematologic toxicities, which may require a dosage adjustment of lamivudine as an individual component
- **Hepatic Impairment:** DOVATO is not recommended in patients with severe hepatic impairment (Child-Pugh Score C)

At Week 48, BIKTARVY had statistically significantly more participants who gained >5% of their baseline weight vs DOVATO

PASO DOBLE

Proportion of participants with weight change >5% of baseline[2]



*Adjusted by baseline value, sex, presence of TAF in previous ART, age, and ethnicity.

For the average participant in the study, 5% of body weight was ~8 lb[11]

The adjusted odds ratio* at Week 48 was 1.81 (95% CI; 1.19, 2.76; *P*=0.006) with fewer DOVATO participants gaining >5% of baseline weight[2]

Weight gain >5% of baseline at Week 48 was a prespecified secondary endpoint. Data from Weeks 6 and 24 were not specified endpoints.[9]

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- Do not use DOVATO in patients with previous hypersensitivity reaction to dolutegravir or lamivudine
- Do not use DOVATO in patients receiving dofetilide

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information, including Boxed Warning, for DOVATO.

Dovato
dolutegravir 50 mg/
lamivudine 300 mg tablets

ViiV Healthcare

New data from 2 head-to-head trials comparing DOVATO vs BIKTARVY

DYAD | PASO DOBLE

Noninferior efficacy of DOVATO vs BIKTARVY

DOVATO was noninferior to BIKTARVY at Week 48 in DYAD and PASO DOBLE[1,2]

DOVATO has a high barrier to resistance

In DYAD and PASO DOBLE, DOVATO had **comparable levels of treatment-emergent resistance** vs BIKTARVY. Additionally, DOVATO had no cases of INSTI resistance[1,2]

Head-to-head weight data

In PASO DOBLE, participants receiving DOVATO experienced **statistically significantly less weight gain** than those on BIKTARVY at Week 48[2]

DYAD is a single-center study conducted in the US.[1]
PASO DOBLE is a multicenter study conducted in Spain.[2]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions

Hypersensitivity Reactions:

- Hypersensitivity reactions have been reported with dolutegravir and were characterized by rash, constitutional findings, and sometimes organ dysfunction, including liver injury
- Discontinue DOVATO immediately if signs or symptoms of severe skin or hypersensitivity reactions develop, as a delay in stopping treatment may result in a life-threatening reaction. Clinical status, including liver aminotransferases, should be monitored and appropriate therapy initiated

Please see additional Important Safety Information throughout.
Please see accompanying full Prescribing Information, including Boxed Warning, for DOVATO.

Dovato
dolutegravir 50 mg/
lamivudine 300 mg tablets

ViiV Healthcare

References:

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7. De Wit S, Bonnet F. Osiyemi O, et al. Durable efficacy of switching from a 3- or 4-drug tenofovir alafenamide–based regimen to the 2-drug regimen dolutegravir/lamivudine in the TANGO study through week 196. *J Acquir Immune Defic Syndr*. 2024;96(2):156-160. doi:10.1097/QAI.0000000000003395
8. Rolle C-P, Castano J, Nguyen V, Hinestrosa F, DeJesus E. Efficacy, safety and tolerability of switching to dolutegravir/lamivudine in virologically suppressed adults living with HIV on bictegravir/emtricitabine/tenofovir alafenamide—the DYAD study. Presented at: IDWeek 2023; October 11-15, 2023; Boston, MA. Abstract ID #1603.
9. ClinicalTrials.gov. DTG/3TC vs. BIC/FTC/TAF maintenance therapy in people living with HIV:(PASO-DOBLE). NCT04884139. Updated August 25, 2023. Accessed July 19, 2024.
10. Vandekerckhove L, Trypsteen W, Blomme E, et al. Impact of switch towards 3TC/dolutegravir on the intact and total HIV-1 viral reservoir in the RUMBA study. Presented at: HIV Drug Therapy Glasgow; October 23-26, 2022; Virtual and Glasgow, Scotland. Slides MO42.
11. Data on file, ViiV Healthcare.

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