3-Year Results

DOVATO is indicated for the treatment of HIV-1 in adults and adolescents above 12 years weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Dovato
dolutegravir/lamivudine

POWER REIMAGINED

AN INNOVATIVE, GUIDELINE-RECOMMENDED REGIMEN FOR YOUR PATIENTS LIVING WITH HIV

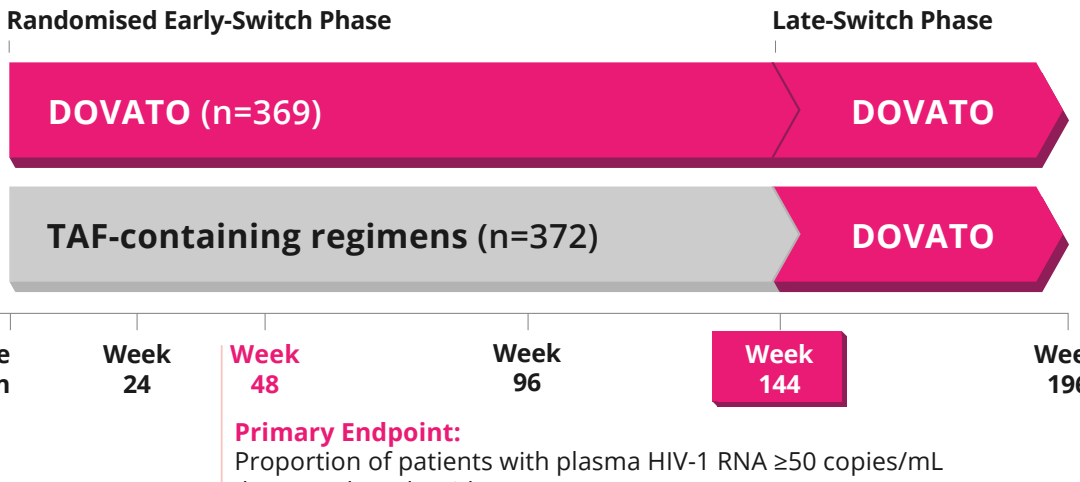
GSK ViiV Healthcare

TANGO

DOVATO vs TAF-CONTAINING REGIMENS IN VIROLOGICALLY SUPPRESSED PATIENTS

Phase III, Randomised, Non-Inferiority Trial With More Than 700 Patients[1]

- Virologically suppressed adults with HIV-1 RNA <50 copies/mL for >6 months
- TAF/FTC + PI or INI or NNRTI as initial regimen
- Stable TAF-containing regimen
- No prior virological failure and no documented NRTI or INI resistance
- HBV negative

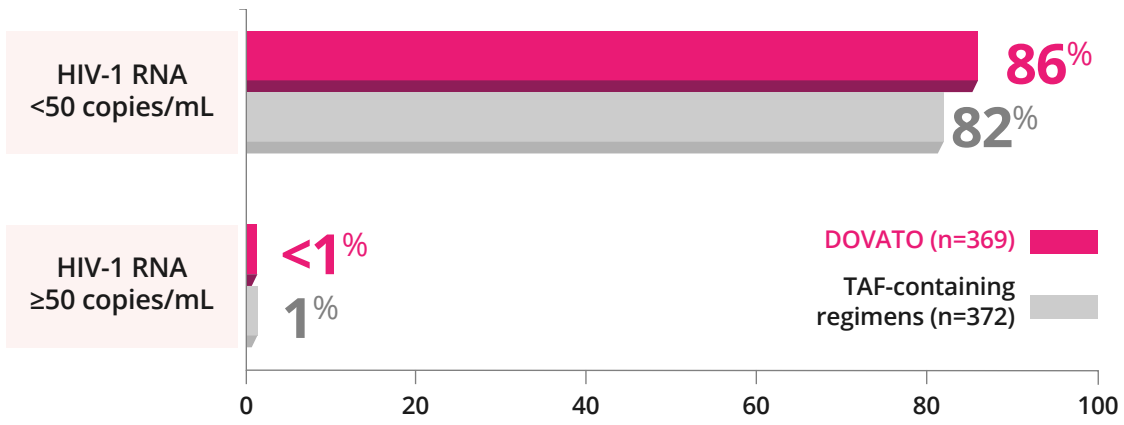


Primary Endpoint:
Proportion of patients with plasma HIV-1 RNA ≥50 copies/mL (by Snapshot algorithm; ITT–E)

POWERFUL, DURABLE EFFICACY OUT TO 3 YEARS

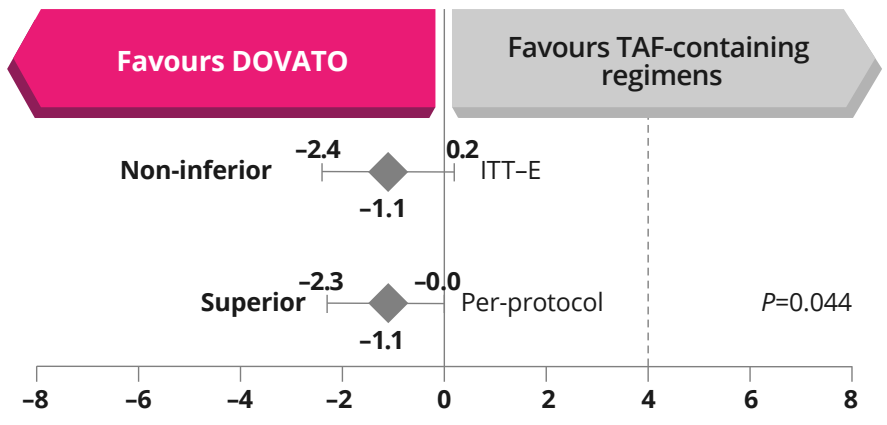
Superior Efficacy in Per-Protocol Analysis and Non-Inferiority in ITT–E at 3 Years[1]

Virological Outcomes



ITT–E Snapshot analysis.

Adjusted Treatment Difference (95% CI)



Adapted from van Wyk et al, 2021.[1]

DOVATO: Reassurance With a High Barrier to Resistance

0 Confirmed Virological Withdrawals*

0 Cases of Resistance-Associated Mutations at 3 Years

—TAF-containing regimens: 3 CVWs
—No INI mutations observed
—No NRTI mutations observed (including M184V/I)

TDF, TAF AND ABC FREE

A 3-Year Tolerability Profile You Expect From DTG and 3TC[1]

Overall AEs, and drug-related AEs after Week 48, were comparable between arms

Beyond Suppression: Metabolic Health at 3 Years

Lipids
Changes in lipids continued to **generally favour DOVATO**

Fasting Glucose and Insulin Resistance
- Small changes in fasting glucose across arms
- Similar increase in HOMA-IR† levels observed in both treatment arms

Weight Gain†
Mean weight changes were comparable between DOVATO (+2.2 kg) and TAF-containing regimens (+1.7 kg), and consistent with what would be expected in the general population

Metabolic Syndrome
ACROSS ARMS:
- Small increases in metabolic syndrome‡

Date of preparation: November 2023 PM-IE-DLL-OGM-210002

Dovato
dolutegravir/lamivudine

Abridged Prescribing Information

Dovato (dolutegravir 50mg/lamivudine 300mg) tablets
See Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Film-coated tablet containing dolutegravir sodium equivalent to 50 mg dolutegravir and 300 mg lamivudine debossed with "SV-137" on one face. **Indication:** HIV-1 in adults & adolescents above 12 years of age weighing >40kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine. **Dosing:** One tablet once daily with or without food. Use an additional 50mg tablet of dolutegravir approximately 12 hours after the dose of Dovato when co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin. *Elderly:* Limited data in 65+ yrs. *Renal impairment:* Not recommended in patients with creatinine clearance < 30 mL/min. For patients with a sustained creatinine clearance between 30 and 49 mL/min see SmPC section 4.4. H*epatic impairment:* Caution in severe hepatic impairment (Child-Pugh grade C). **Contraindications:** Hypersensitivity to any ingredient. Co-administration with substrates of OCT-2 with narrow therapeutic windows, such as fampridine. **Special warnings/precautions:** Risk of hypersensitivity reactions. Discontinue dolutegravir and other suspect agents immediately. Risks of osteonecrosis, immune reactivation syndrome. Monitor LFTs in Hepatitis B/C co-infection and ensure effective Hepatitis B therapy. Caution with metformin: monitor renal function and consider metformin dose adjustment. Use with etravirine requires boosted PI or increased dose of dolutegravir. Use with Mg/Al-containing antacids requires dosage separation. Use with calcium, multivitamins or iron also requires dosage separation if not taken at the same time with food. Use with cladribine or emtricitabine not recommended. When possible, avoid chronic co-administration of sorbitol or other osmotic acting alcohols (see SmPC section 4.5). If unavoidable, consider more frequent viral load monitoring. **Fertility, pregnancy and lactation:** Human fertility - no data; animal fertility - studies indicate no effects. Women of childbearing potential (WOCBP) should be counselled about the potential risk of neural tube defects including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment should be discussed with the patient. The safety and efficacy of a duel regime has not been studied in pregnancy. If a pregnancy is confirmed in the first trimester while on Dovato, the benefits and risks of continuing Dovato versus switching to another antiretroviral regimen should be discussed with the patient taking the gestational age and the critical time period of neural tube defect development into account (see SmPC section 4.6). There have been reports of mitochondrial dysfunction in HIV-negative infants exposed in utero and/or post-natally to nucleoside analogues. Do not breast-feed. **Side effects:** See SmPC for full details. Headache, GI disturbance, insomnia, abnormal dreams, depression, anxiety, dizziness, somnolence, rash, pruritus, alopecia, fatigue, arthralgia, myalgia, hypersensitivity, completed suicide, suicidal ideation or suicide attempt, panic attack, hepatitis, blood dyscrasias, acute hepatic failure, pancreatitis, angioedema, rhabdomyolysis, lactic acidosis, peripheral neuropathy. Elevations of bilirubin, ALT, AST and CPK. Weight increased. **MA Nr:** EU/1/19/1370/001. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. **Legal Category:** POM A. **Date of preparation of API:** September 2022. **Code:** PI-6305. Further information available from GlaxoSmithKline, 12 Riverwalk, Citywest, Business Campus, Dublin 24. Tel: 01-4955000.

Adverse events should be reported directly to the Health Products Regulatory Authority (HPRA) on their website: www.hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

*Patients met confirmed virological withdrawal criteria if they had 1 assessment with HIV-1 RNA ≥200 copies/mL after Day 1 with an immediately prior HIV-1 RNA ≥50 copies/mL.[2]
†Defined as homeostatic model assessment of insulin resistance (HOMA-IR) ≥2.[2]
‡Metabolic syndrome defined by the International Diabetes Federation as a combination of risk factors for cardiovascular disease.[3]

References: 1. van Wyk J et al. Presented at: 11th IAS Conference on HIV Science; July 18-21, 2021; Virtual. Poster PEB164. **2.** van Wyk J et al. *Clin Infect Dis*. 2020;71(8):1920-1929. doi:10.1093/cid/ciz1243. **3.** International Diabetes Federation. Published 2006. Updated April 5, 2017. Last Accessed: May 2022. Available at: https://www.idf.org /e-library/consensus-statements /60-idfconsensus-worldwide-definitionof-the-metabolic-syndrome.html.

Dovato
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