POWER REIMAGINED

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

48-Week Results

DOVATO is indicated for the treatment of HIV-1 in adults and adolescents above12 years weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Dovato
dolutegravir/lamivudine

DOVATO vs CURRENT ANTIRETROVIRAL REGIMENS IN DIVERSE VIROLOGICALLY SUPPRESSED PATIENTS

Phase III, Randomised, Open-Label, Multicentre Non-Inferiority Trial With ~500 Patients[1]

- Virologically suppressed adults with HIV-1 RNA <50 copies/mL
- Stable current regimen (2 NRTIs + INI, NNRTI or PI) for ≥3 months
- No prior virological failure and no documented NRTI or INI resistance
- HBV negative and no need for HCV therapy

Randomised Phase (Day 1-Week 52)

DOVATO (n=246)

Continued current regimens (n=247)

Screening → **Day 1 Baseline Randomisation 1:1** → **Week 24** → **Week 48** → **Week 52**

Primary Endpoint:
Patients with plasma HIV-1 RNA ≥50 copies/mL per FDA Snapshot (ITT–E)

A Diverse Patient Population

Demographics

- **39%** Female
- **39%** ≥50 Years
- **19%** African American/ African Heritage
- **14%** Asian
- **59%** White

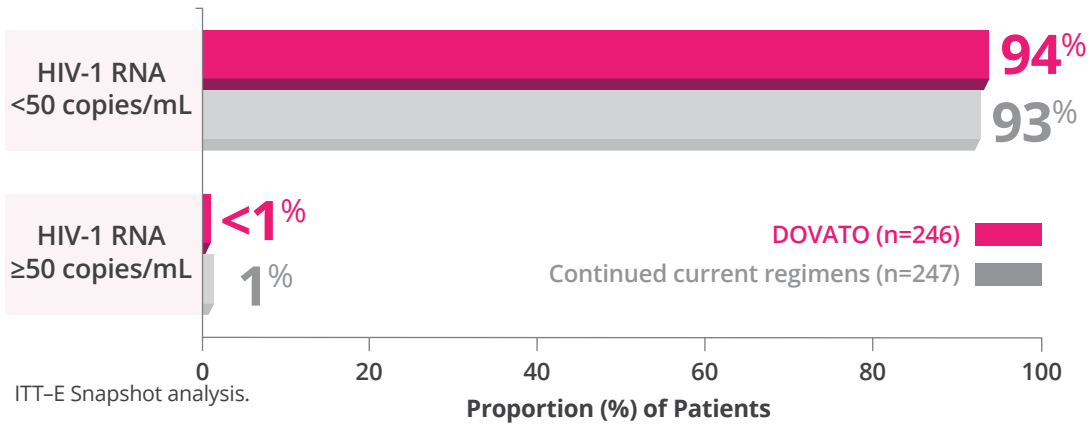
Baseline Regimens

- **40%** INIs
- **44%** TDF
- **50%** NNRTIs
- **35%** TAF

POWERFUL EFFICACY AND A HIGH BARRIER TO RESISTANCE OUT TO 48 WEEKS

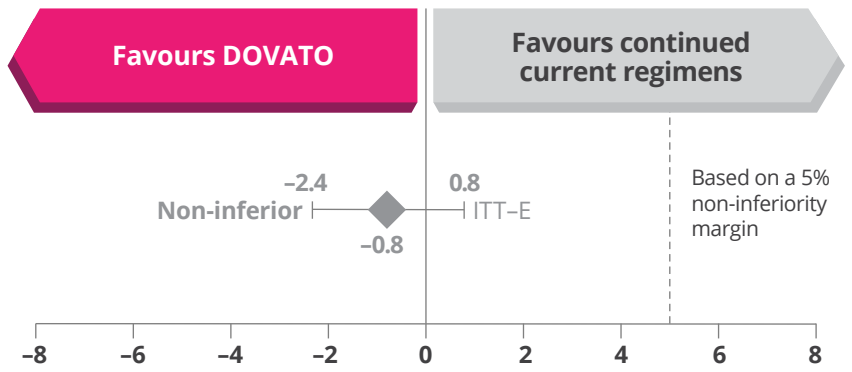
Non-Inferiority Maintained With No Increased Risk of Virological Failure vs Continued Current Regimens[1]

Virological Outcomes



ITT–E Snapshot analysis.

Adjusted Treatment Difference (95% CI)



Adapted from Llibre et al, 2021.[1]

Reassurance With a High Barrier to Resistance

0 Confirmed Virological Withdrawals*

0 Cases of Resistance-Associated Mutations

Across Both Arms

TDF, TAF AND ABC FREE

Drug-Related AEs Leading to Withdrawal Were Comparable Across Arms at 48 Weeks[1]

- **Drug-related AEs:** DOVATO 20% (n=48/246) vs continued current regimens 6% (n=16/247)
- **Drug-related AEs leading to withdrawal:** DOVATO 2% (n=4/246) vs continued current regimens <1% (n=1/247)
- **No serious drug-related AEs** in either arm

Beyond Suppression: Metabolic Health Parameters at 48 Weeks[1]

Lipids

Changes in lipid parameters were **small and similar between treatment arms**

Bone and Renal Biomarkers

- **Improvements across bone biomarkers favoured DOVATO**, suggesting improved bone turnover vs continued current regimens
- **Changes in proximal renal function favoured DOVATO**, suggesting some improvement in kidney function
- **Similar small changes in eGFR by cystatin C** were observed in both treatment groups

Weight Gain

- Adjusted mean change in weight from baseline to Week 48 was +2.1 kg in the DOVATO arm vs +0.6 kg in the continued current regimen arm
  - —44% (n=109/246) of patients in the DOVATO arm were switched from regimens with TDF

Inflammatory Biomarkers

Changes were generally similar between groups, with the exception of **soluble CD14 changes favouring DOVATO**

Date of preparation: November 2023 | PM-IE-DLL-OGM-210004

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. *Hepatic 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.

*Confirmed virological withdrawal criteria defined as 1 assessment of HIV-1 RNA ≥200 copies/mL after Day 1 with an immediately prior HIV-1 RNA ≥50 copies/mL.[1]

Reference: 1. Llibre JM et al. Presented at: 11th IAS Conference on HIV Science; July 18-21, 2021; Virtual. Slides OALB0303.

Date of preparation: November 2023 PM-IE-DLL-OGM-210004