# STAT

## 48-Week 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

## CONFIDENCE IN DOVATO FOR YOUR NEWLY DIAGNOSED PATIENTS

### Feasibility, Efficacy and Safety of Using Dovato as a First-Line Regimen in a Test-and-Treat Setting[1,2]

**DOVATO** (N=131)

**Screening/Day 1**
ART-naïve adults ≥18 years of age and diagnosed with HIV within 14 days of study entry

**Week 1**
Review baseline safety lab results, including HBV co-infection

**Week 4**
Review baseline HIV-1 resistance data

**Week 8**

**Week 12**

**Week 24**
**Primary endpoint:** Proportion of patients with plasma HIV-1 RNA <50 copies/mL (ITT–E analysis)

**Week 48**
**Key secondary efficacy analysis:** Proportion of patients with plasma HIV-1 RNA <50 copies/mL

**Week 52**

### Unknown Baseline Values at Treatment Initiation[1]*

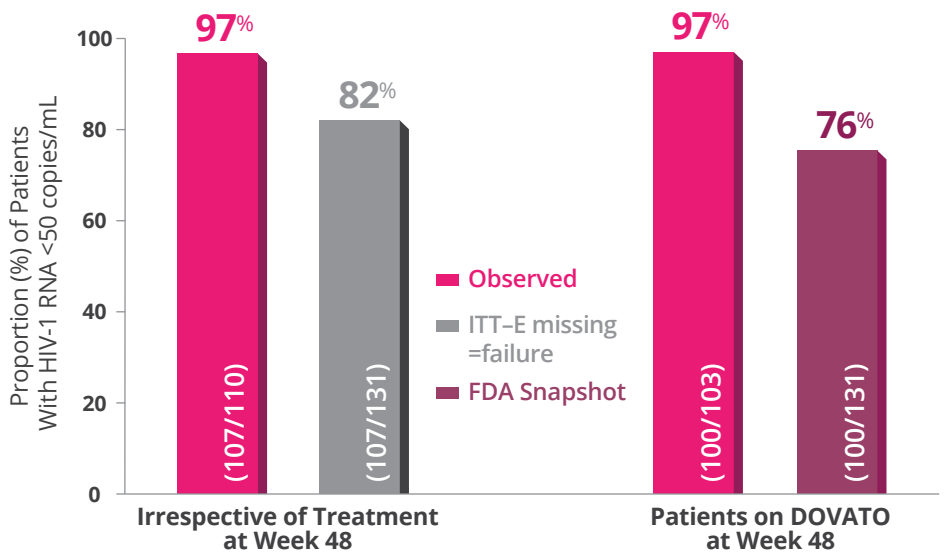
- **HIV-1 RNA copies/mL**
  - —15% >500,000 copies/mL (n=19/131)
- **CD4⁺ T-cell count cells/mm³**
- **HBV co-infection**
- **Baseline resistance**

**26% of patients were diagnosed and initiated on DOVATO same day (n=34/131)**

## DOVATO DEMONSTRATED POWERFUL EFFICACY AND 0 RESISTANCE AT WEEK 48

AMONG PATIENTS WITH AVAILABLE HIV-1 RNA AT WEEK 48,
**97% ACHIEVED VIROLOGICAL SUPPRESSION ON DOVATO[1]**

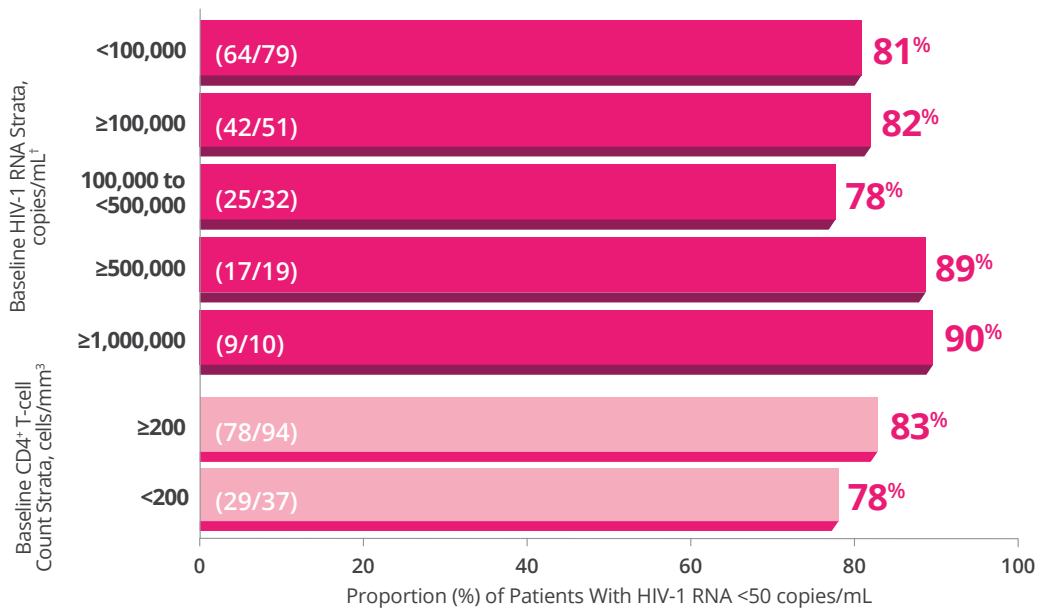
### Virological suppression at Week 48




- **0** discontinuations due to lack of efficacy

**EFFICACY WAS CONSISTENT ACROSS BASELINE VIRAL LOADS, INCLUDING THOSE ≥1 MILLION copies/mL[1]**

### Virological outcomes by baseline viral load or CD4⁺ T-cell count (ITT–E Missing=Failure Analysis)




### Reassurance With a High Barrier to Resistance[1]

**0** **Treatment-Emergent HIV-1 Resistance Was Observed**

**2 participants met criteria for confirmed virological failure; both remained on DOVATO**

## REASSURANCE WITH FEW TREATMENT MODIFICATIONS

### A Tolerability Profile You Expect From a DTG-Based Regimen

**Reported Adverse Events (AEs) for DOVATO were in-line with the Summary of Product Characteristics[1]:**

- AEs occurring in ≥7% of patients: headache 9% (n=12/131), diarrhoea 8% (n=10/131), depression 7% (n=9/131) and nausea 7% (n=9/131)
- 3% (n=2/131) of patients experienced drug-related AEs, Grade 2 to Grade 5

### Reasons for Modification by Week 48 (n=10/131)[1‡]

**4%** **Baseline HBV (n=5/131)**
- 0 patients developed HBV resistance to lamivudine when switching from DOVATO

**<1%** **Baseline M184V resistance mutations (n=1/131)**
- Patient achieved HIV-1 RNA <50 copies/mL by Week 8 before ART regimen modification

**<1%** **AE, Rash (n=1/131)**

**<2%** **Decision by Patient (n=3/131)[§]**

- **7 out of 10 patients with available virological data at Week 48 had HIV-1 RNA <50 copies/mL**

Date of preparation: November 2023 PM-IE-DLL-OGM-210003

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.

**KEY EFFICACY ANALYSIS DEFINITIONS:**

**Observed:** Proportion of participants with plasma HIV-1 RNA <50 copies/mL, regardless of ART regimen, among those with available HIV-1 RNA at Week 24.
**Intention-to-treat–exposed (ITT–E) missing=failure:** Proportion of all participants with plasma HIV-1 RNA <50 copies/mL at Week 24, regardless of ART regimen.
**FDA Snapshot:** Proportion of all participants with plasma HIV-1 RNA <50 copies/mL at Week 24 still taking DOVATO.

*Treatment was adjusted if baseline testing indicated the presence of HBV, genotypic resistance to DTG or 3TC, or creatinine clearance <30 mL/min/1.73 $m^2$.
†One (<1%) participant had missing plasma HIV-1 RNA results at baseline.[1]
‡One participant was switched post-Week 48 HIV-1 RNA assessment (after 831 copes/mL assessment); HIV-1 RNA was 51 copies/mL at last follow-up visit.
§Includes 1 pregnancy.

**References: 1.** Rolle C-P et al. Presented at: 11th IAS Conference on HIV Science; July 18-21, 2021; Virtual. Poster PEB182. **2.** Rolle C-P et al. *AIDS*. 2021. doi:10.1097/QAD.0000000000002979



Dovato
dolutegravir/lamivudine