gemini 1 gemini 2

144-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

DOVATO vs DTG + TDF/FTC IN TREATMENT-NAÏVE PATIENTS

2 Fully Powered, Phase III, Double-Blind Clinical Trials With More Than 1,400 Patients Combined[1]

GEMINI-1 and GEMINI-2 (pooled)
- Treatment-naïve adults (≥18 years old)
- Screening viral load 1,000 to 500,000 copies/mL
- HBV negative
- No major resistance-associated mutations
- CrCl > 50mL/min

Double-Blind Phase | **Open-Label Phase**

DOVATO (n=716)

DTG 50 mg + TDF/FTC 300 mg/200 mg (n=717)

Screening (28 days)

Baseline Randomisation

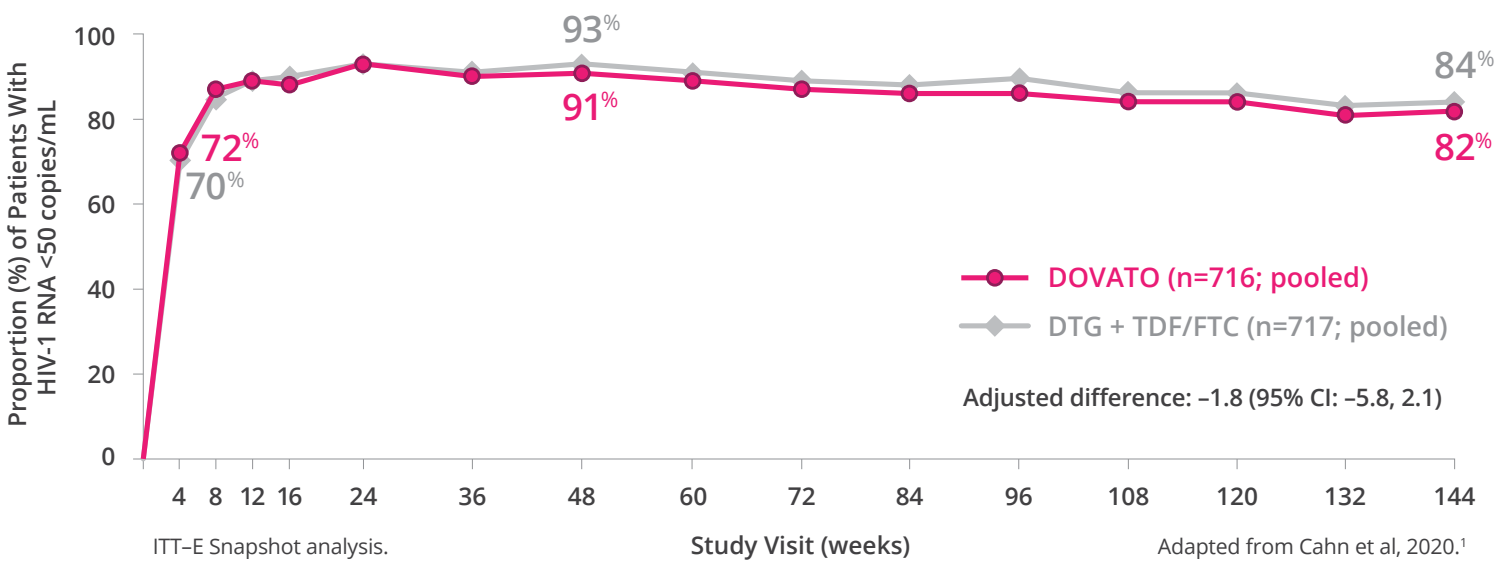
DTG 50 mg + 3TC 300 mg used in the GEMINI studies.

Week 48
Primary Endpoint:
Proportion of patients with plasma HIV-1 RNA <50 copies/mL (by Snapshot algorithm; ITT–E)

Week 96

Week 144

RAPID, POWERFUL AND DURABLE NON-INFERIOR EFFICACY VS A 3-DRUG REGIMEN



ITT–E Snapshot analysis.

Adapted from Cahn et al, 2020.[1]

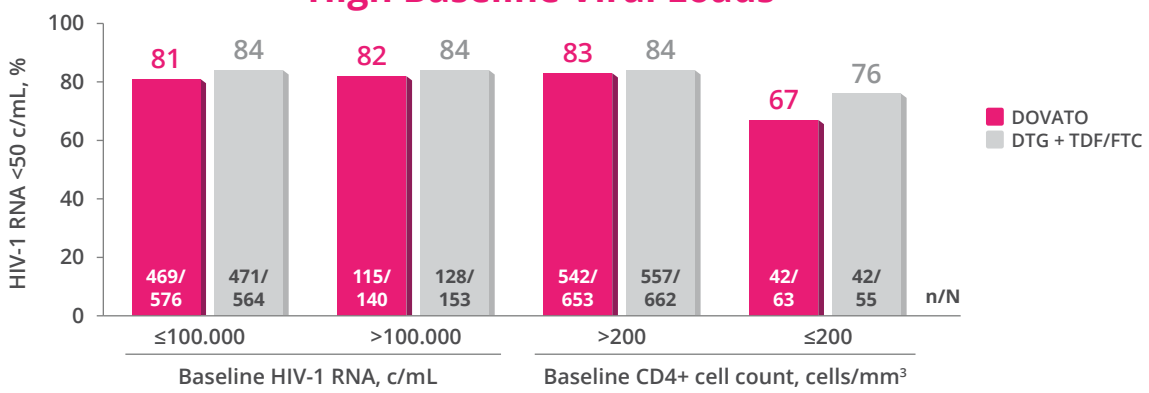
DOVATO Virological Suppression

Rapid: **72% at Week 4**

Powerful: **91% at Week 48**

Durable: **82% at 144 Weeks**

Durable Suppression in Patients With High Baseline Viral Loads



ITT–E pooled analysis.
Adapted from Cahn et al, 2020.[1]

A PROVEN HIGH BARRIER TO RESISTANCE

- Few confirmed virological withdrawals*:
  - —DOVATO: 12 (2%)
  - —DTG + TDF/FTC: 9 (1%)
- One participant with documented non-adherence developed resistance-associated mutations (M184V and R263R/K) while taking DTG + 3TC separates; the participant was successfully switched to DTG + DRV/c

TDF, TAF AND ABC FREE

Overall, adverse event profiles were comparable across both arms at week 144

- **Any AE:** DOVATO 86% (613/716) vs DTG + TDF/FTC 87% (625/717)
- **AEs leading to withdrawal:** DOVATO 4% (31/716) vs DTG + TDF/FTC 5% (33/717)

Lower rate of drug-related adverse events vs DTG + TDF/FTC[1‡]

- Frequently reported adverse reactions include headache (3%), diarrhoea (2%), nausea (2%) and insomnia (2%).[2]

20% DOVATO (n=146/716) — vs — **27%** DTG + TDF/FTC (n=192/717)

†The relative risk ratio (95% CI) for DOVATO vs DTG + TDF/FTC was 0.76 (0.63, 0.92).[1]

Bone and Renal Biomarkers at 144 weeks With DOVATO[1]

Changes in bone turnover biomarkers significantly favour DOVATO vs DTG + TDF/FTC‡

Changes in renal function biomarkers significantly favour DOVATO vs DTG + TDF/FTC‡
— AEs due to renal and urinary disorders were comparable across both arms

Changes in lipid parameters generally favoured DTG + TDF/FTC through week 144

‡The GEMINI studies did not determine whether these changes translate to clinical differences.

Dovato
dolutegravir/lamivudine

Prescribing Information

Dovato dolutegravir 50mg/lamivudine 300mg tablets
See Summary of Product Characteristics (SmPC) before prescribing

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. Not recommended in patients with creatinine clearance < 50 mL/min. Caution in severe hepatic impairment. **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. **Pregnancy/ lactation:** The safety and efficacy have not been studied in pregnancy. Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Dovato), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Dovato should be discussed with the patient. 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. Most neural tube defects occur within the first 4 weeks of embryonic development after conception (approximately 6 weeks after the last menstrual period). Dovato may be used during the second and third trimester of pregnancy when the expected benefit justifies the potential risk to the foetus. 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, suicidal ideation or suicide attempt, hepatitis, blood dyscrasias, acute hepatic failure, pancreatitis, angioedema, rhabdomyolysis, lactic acidosis, peripheral neuropathy. Elevations of ALT, AST and CPK. **Basic NHS costs:** £656.26 for 30 tablets. **MA number:** EU/1/19/1370/001. **MA holder:** ViiV Healthcare BV, Van Asch van Wijckstraat 55H, 3811 LP Amersfoort, Netherlands. Further information available from: customercontactuk@gsk.com
Freephone 0800 221 441.

POM

Date of approval: July 2020 PI-2451v4

Adverse events should be reported. For the UK, reporting forms and information can be found at *www.mhra.gov.uk/yellowcard* or search for **MHRA Yellowcard** in the **Google Play** or **Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.

*Patients met confirmed virological withdrawal criteria if a second and consecutive HIV-1 RNA value met any of the following definitions: decrease from baseline in HIV-1 RNA of <1 $\log_{10}$ copies/mL unless HIV-1 RNA <200 copies/mL by Week 12; confirmed plasma HIV-1 RNA of ≥200 copies/mL after confirmed consecutive HIV-1 RNA <200 copies/mL.[1]

Reference: 1. Cahn P, Sierra Madero J, Arribas JR, et al. Durable efficacy of dolutegravir (DTG) plus lamivudine (3TC) in antiretroviral treatment–naive adults with HIV-1 infection—3-year results from the GEMINI studies. Presented at: HIV Glasgow 2020; October 5-8, 2020; Virtual. Poster P018. **2.** DOVATO (dolutegravir/lamivudine) Summary of Product Characteristics.

ViiV Healthcare

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Veeva Vault

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Product: DOVATO

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Role	Signature
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