Dovato
dolutegravir/lamivudine

POWER REIMAGINED

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.

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]

STAT

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
Proportion of patients with plasma HIV-1 RNA <50 copies/mL

Week 48
Proportion of patients with plasma HIV-1 RNA <50 copies/mL

UNKNOWN BASELINE VALUES AT TREATMENT INITIATION[1]*

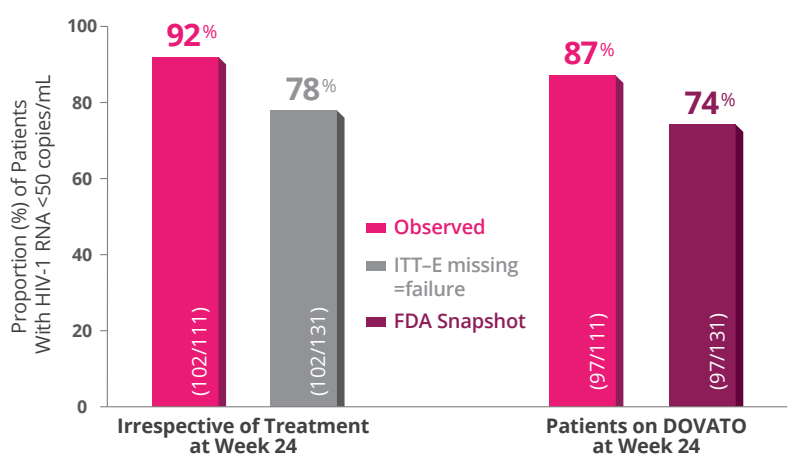
- HIV-1 RNA copies/mL
- CD4+ T-cell count cells/mm³
- HBV co-infection
- Baseline resistance

DOVATO DEMONSTRATED POWERFUL EFFICACY* AT WEEK 24

*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.
As a single arm study comparisons of efficacy can not be made with other treatment regimens.

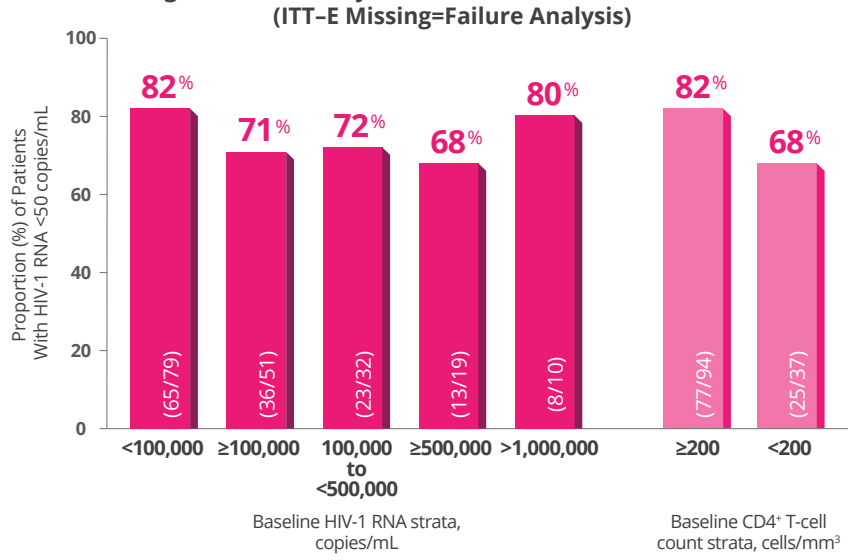
AMONG PATIENTS WITH AVAILABLE HIV-1 RNA AT WEEK 24,
87% ACHIEVED VIROLOGICAL SUPPRESSION ON DOVATO[1]

Virological suppression at Week 24



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)



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

REASSURANCE WITH 0 RESISTANCE AND FEW TREATMENT MODIFICATIONS

0

TREATMENT-EMERGENT HIV-1 RESISTANCE WAS OBSERVED[1]

- **0** patients developed HBV resistance to lamivudine

REASONS FOR MODIFICATION BY WEEK 24[1]

- **4%** **Baseline HBV (n=5/131)**
- **<1%** **Baseline M184V resistance mutations (n=1/131).** Patient achieved HIV-1 RNA <50 copies/mL by Week 8 before ART regimen modification to DTG/RPV
- **<1%** **Adverse Event, Rash (n=1/131)**
- **<1%** **Decision by Patient (n=1/131)**

- **5 out of 8 patients with available virological data at Week 24 had HIV-1 RNA <50 copies/mL**

A TOLERABILITY PROFILE YOU HAVE COME TO EXPECT FROM A DTG-BASED REGIMEN

Reported AEs for DOVATO were in-line with the Summary of Product Characteristics[1]:

- AEs occurring in >5% of patients: headache (8%), diarrhoea (6%), fatigue (6%)
- 7% of patients experienced a drug-related AE

Dovato is not recommended for use in patients with a creatinine clearance < 50 mL/min.

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-2451 v4

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.

Prescribing Information

Juluca▼ dolutegravir 50mg/rilpivirine 25mg tablets

See Summary of Product Characteristics before prescribing

Indication: : HIV-1 in virologically suppressed adults (HIV-1 RNA <50 copies/mL) on stable ART for at least 6 months with no history of virological failure and no known resistance to any NNRTI or INI. **Dosing:** *Adults (over 18 years)*: one tablet once daily **with food**. *Elderly*: Limited data in 65+ yrs. Caution in severe hepatic or renal impairment. **Contraindications:** Hypersensitivity to any ingredient. Co-administration with carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, rifapentine, proton pump inhibitors, systemic dexamethasone (excluding single dose), St John's Wort or fampridine. **Special warnings/precautions:** Risk of hypersensitivity reactions. Discontinue Juluca immediately if suspected. Risks of prolongation of QTc interval, osteonecrosis, opportunistic infections, immune reactivation syndrome. Monitor LFTs in Hepatitis B/C co-infection and ensure effective Hepatitis B therapy. Small rise in serum creatinine in first 4 weeks of treatment, not considered clinically relevant. Do not co-administer with other antiretrovirals (except in case of co-administration of rifabutin, when an extra dose of rilpivirine 25mg should be used). Use with antacids or once-daily H2-receptor antagonists requires dosage separation. Calcium, iron or multivitamins should be taken at the same time as Juluca with food, otherwise dosage separation recommended. Caution with metformin: monitor renal function and consider metformin dose adjustment to minimise risk of lactic acidosis. If macrolide antibiotics are required, consider azithromycin. Caution with antimalarials (artemether/lumefantrine) or anticoagulants (dabigatran). **Pregnancy/ lactation:** The safety and efficacy have not been studied in pregnancy. Not recommended during pregnancy due to observed lower exposure of dolutegravir and rilpivirine. Women of childbearing potential should be counselled about the potential risk of neural tube defects with dolutegravir (a component of Juluca), including consideration of effective contraceptive measures. If a woman plans pregnancy, the benefits and the risks of continuing treatment with Juluca should be discussed with the patient. Do not breast-feed. **Side effects:** See SmPC for full details. Increased total and LDL cholesterol, insomnia, headache, dizziness, nausea, diarrhoea, increased triglycerides, decreased appetite, abnormal dreams, depression, anxiety, sleep disorders, GI disorders, rash, pruritus, fatigue, decreased white blood cell count, haemoglobin and platelet count, arthralgia, myalgia, hypersensitivity, hepatitis, suicidal ideation or suicide attempt, acute hepatic failure. Changes in laboratory biochemistries: elevations of ALT, AST, pancreatic amylase, bilirubin and CPK. **Basic NHS costs:** £699.02 for 30 tablets (EU/1/18/1282/001). **MA number:** EU/1/18/1282/001. **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 S1A

Date of approval: July 2020 PI-0396v4

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.

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.

References: 1. Rolle C-P, Berhe M, Singh T, et al. Feasibility, efficacy, and safety of using dolutegravir/lamivudine (DTG/3TC) as a first-line regimen in a test-and-treat setting for newly diagnosed people living with HIV (PLWH): The STAT study. Presented at: 14th annual American Conference for the Treatment of HIV; August 20-22, 2020; Virtual. **2.** ViiV Healthcare. Rapid test and treat dolutegravir plus lamivudine study in newly diagnosed human immunodeficiency virus (HIV)-1 infected adults. NCT03945981. ClinicalTrials.gov. Updated May 7, 2020. Accessed August 7, 2020. https://clinicaltrials.gov/ct2/show/NCT03945981

ViiV Healthcare

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Role	Signature
Thomas Van Every - Medical Affairs (thom.x.van-every@gsk.com)	It is approved that this material has been examined and is believed to be in accordance with the relevant Code of Practice and any other relevant regulations, policies and SOPs. Date: 03-Sep-2020 15:26:37 GMT+0000
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