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.

FEASIBILITY, EFFICACY AND SAFETY OF USING DOVATO AS A FIRST-LINE REGIMEN IN A TEST-AND-TREAT SETTING

DOVATO (N=131)

Week 1
Review baseline
HIV-1 resistance data

Week 4
Review baseline safety lab results, including HBV co-infection

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

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

DOVATO DEMONSTRATED POWERFUL EFFICACY AT WEEK 24

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

Virological suppression at Week 24

Patient's on DOVATO at Week 24

Proportion (%) of Patients With HIV-1 RNA <50 copies/mL

Virological outcomes by baseline viral load or CD4+ T-cell count

(ITT-E Missing=Failure Analysis)

Baseline HIV-1 RNA strata, copies/mL
<100,000
100,000 to <500,000
500,000 to 1,000,000
>1,000,000

Baseline CD4+ T-cell count strata, cells/mm³
<200
≥200

• 0 discontinuations due to lack of efficacy

REASSURANCE WITH 0 RESISTANCE AND FEW TREATMENT MODIFICATIONS

TREATMENT-EMERGENT HIV-1 RESISTANCE WAS OBSERVED

• 0 patients developed HBV resistance to lamivudine

REASONS FOR MODIFICATION BY WEEK 24

4% Baseline HBV (n=5/131)
<1% Baseline M184V resistance mutations (n=1/131).
<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:

- AEs occurring in >5% of patients: headache (8%), diarrhoea (6%), fatigue (6%)
- 7% of patients experienced a drug-related AE
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, oxicarbazine, 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. 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 dual 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, suicidal ideation or suicide attempt, hepatitis, blood dyscrasias, acute hepatic failure, pancreatitis, angioedema, rhabdomyolysis, lactic acidosis, peripheral neuropathy. Elevations of ALT, AST and CPK. 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: July 2020. Code: PI-6305. Further information available from GlaxoSmithKline, 12 Riverwalk, Citywest, Business Campus, Dublin 24. Tel: 01-4955000.

Adverse events should be reported to the Health Products Regulatory Authority (HPRA) using an Adverse Reaction Report Form obtained either from the HPRA or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 6764971. 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, regardless of ART regimen, among those with available HIV-1 RNA 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 m².  