



BEHIND THE STUDIES

Two identical ongoing Phase III studies investigating the **efficacy** and **safety** of switching to a **DTG + RPV two-drug regimen** (2DR) in virologically suppressed **HIV-1** infected adults.¹ These are the first registrational studies investigating a 2DR.

WEEK 48 RESULTS FOR DTG + RPV DEMONSTRATED:



95% of patients maintained virological suppression (n=486)¹



Zero failures with resistance to DTG¹



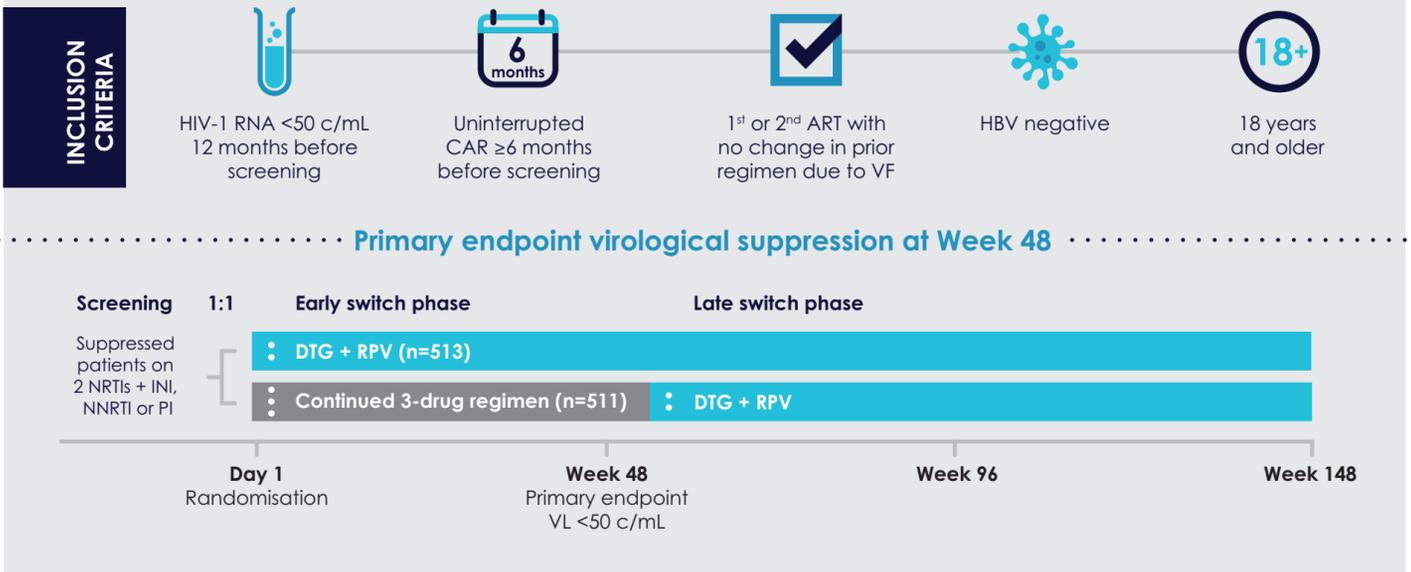
Statistically significant recovery in BMD²



Safety profiles consistent with their respective labels^{3,4}

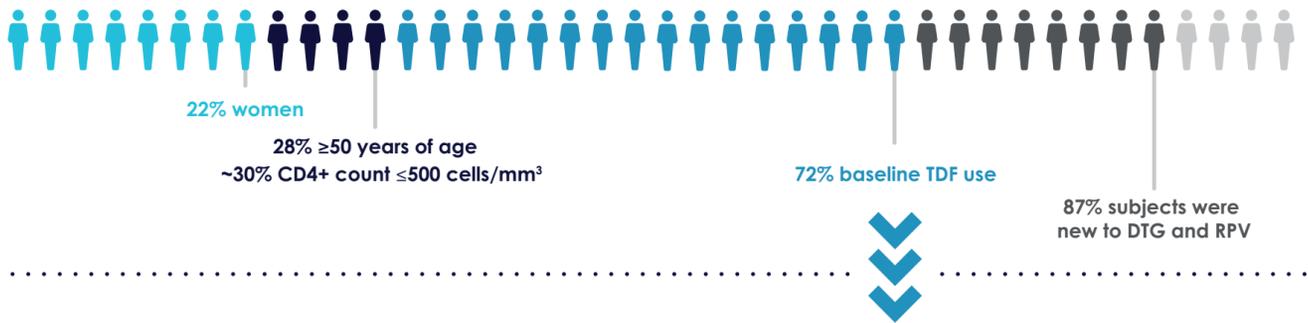
SWORD STUDY DESIGN^{1,5}

Two randomised, multicentre, parallel-group, non-inferiority studies



PATIENT DEMOGRAPHICS

Over 1,000 adult patients in total across a diverse population:^{1,6}



Baseline 3rd-agent class included:¹



DEXA SUB STUDY

102 participants included to evaluate the change in BMD at 48 weeks following switch from TDF-containing regimen to DTG + RPV compared to continuing CAR²

SWORD STUDY LOCATIONS

13 countries, 60+ study sites:^{7,8}

SWORD-1 & -2: Argentina, Australia, Canada, France, Germany, Italy, Russia, Spain, Taiwan, UK, US

SWORD-1 only: Belgium, Netherlands



ABBREVIATIONS

ART, antiretroviral therapy; **BMD**, bone mineral density; **CAR**, current antiretroviral regimen; **DTG**, dolutegravir; **HBV**, hepatitis B virus; **INI**, integrase inhibitor; **NNRTI**, non-nucleoside reverse transcriptase inhibitor; **NRTI**, nucleoside reverse transcriptase inhibitor; **PI**, protease inhibitor; **RPV**, rilpivirine; **TDF**, tenofovir disoproxil fumarate; **VF**, virologic failure; **VL**, viral load; **2DR**, two-drug regimen.

References

1. Llibre JM, et al. *Lancet* 2018;391:839–849.
2. McComsey GA, et al. *AIDS* 2018;32:477–485.
3. Tivicay SmPC.
4. Edurant SmPC.
5. Llibre JM, et al. *CROI* 2017; Seattle, WA. Abstract 2421.
6. Oglesby A, et al. *EACS* 2017; Milan, Italy. Abstract BPD1/2.
7. Clinical Trial: NCT02429791.
8. Clinical Trial: NCT02422797.
9. JULUCA SmPC.

JULUCA▼ (dolutegravir/rilpivirine) is indicated for 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 INI¹



Date of preparation: May 2018. Zinc code: UK/DTGP/0012/18

Prescribing Information

Juluca ▼ dolutegravir 50mg/rilpivirine 25mg tablets
See Summary of Product Characteristics (SmPC) 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 dofetilide, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifampicin, rifapentine, proton pump inhibitors, systemic dexamethasone (excluding single dose) or St John's Wort. **Warnings/precautions:** Risk of hypersensitivity reactions. Discontinue Juluca immediately if suspected. Risks of prolongation of QTc interval, osteonecrosis, opportunistic infections. 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:** Not recommended. Avoid breast-feeding. **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 holder: ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS. Further information available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

POM Date of approval: May 2018

Zinc code: UK/DTGRPV/0030/18

Prescribing Information

Tivicay ▼ dolutegravir 10mg, 25mg and 50mg tablets
See Summary of Product Characteristics before prescribing
Indication: HIV in >6 years and ≥15kg as part of combination therapy. **Dosing:** Adults & adolescents ≥40kg: 50mg once daily with or without food if no proven/ suspected integrase resistance. Children 6 to <12 years: dose according to bodyweight: 15–<20kg: 20mg once daily (2x10mg); 20–<30kg: 25mg once daily; 30–<40kg: 35mg once daily (1 x 25mg + 1 x 10mg); When co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin, Tivicay 50mg twice daily in adults/adolescents or the weight-based once daily dose twice daily in paediatric patients. **Adults with proven/ suspected integrase resistance:** 50mg twice daily preferably with food. Limited data in paediatric patients with proven/suspected integrase resistance. **Elderly:** Limited data in 65+ yrs. Caution in severe hepatic impairment. **Contraindications:** Hypersensitivity to any ingredient. Co-administration with dofetilide. **Warnings/precautions:** Risk of hypersensitivity reactions. Discontinue dolutegravir and other suspect agents immediately if suspected. 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, calcium, multivitamins or iron requires dosage separation. **Pregnancy/ lactation:** Not recommended. Avoid breast-feeding. **Side effects:** See SmPC for full details. Headache, GI disturbance, insomnia, abnormal dreams, depression, anxiety, dizziness, rash, pruritus, fatigue, elevations of ALT, AST and CPK, arthralgia, myalgia, hypersensitivity, suicidal ideation or suicide attempt. **Basic NHS costs:** £498.75 for 30 x 50mg tablets (EU/1/13/892/001); £99.75 for 30 x 10mg tablets (EU/1/13/892/003); £249.38 for 30 x 25mg tablets (EU/1/13/892/005). MA holder: ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS. Further information available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

POM Date of approval: March 2018

Zinc code: UK/DLGO/0055/13/12

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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.

Adverse events should be reported. For Ireland, adverse events should be reported directly to the HPRA: Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Terrace, Dublin 2, Tel: +353 1 676 4971, medsafety@hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.