SWORD-1 SWORD-2

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 DTG[1]
- **Statistically significant recovery** in BMD[2]
- Safety profiles consistent with their respective labels[3,4]

SWORD STUDY DESIGN[1,5]

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

INCLUSION CRITERIA

- HIV-1 RNA <50 c/mL 12 months before screening
- Uninterrupted CAR ≥6 months before screening
- 1st or 2nd ART with no change in prior regimen due to VF
- HBV negative
- 18 years and older

Primary endpoint virological suppression at Week 48

Screening

Suppressed patients on 2 NRTIs + INI, NNRTI or PI

1:1

Early switch phase

- DTG + RPV (n=513)
- Continued 3-drug regimen (n=511)

Late switch phase

- DTG + RPV

Day 1
Randomisation

Week 48
Primary endpoint
VL <50 c/mL

Week 96

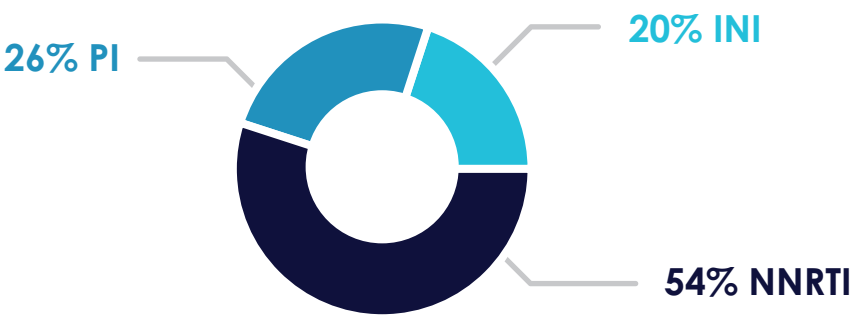
Week 148

PATIENT DEMOGRAPHICS

Over 1,000 adult patients in total across a diverse population:[1,6]

- 22% women
- 28% ≥50 years of age
- ~30% CD4+ count ≤500 cells/mm³
- 72% baseline TDF use
- 87% subjects were new to DTG and RPV

Baseline 3rd-agent class included:[1]



DEXA SUB STUDY

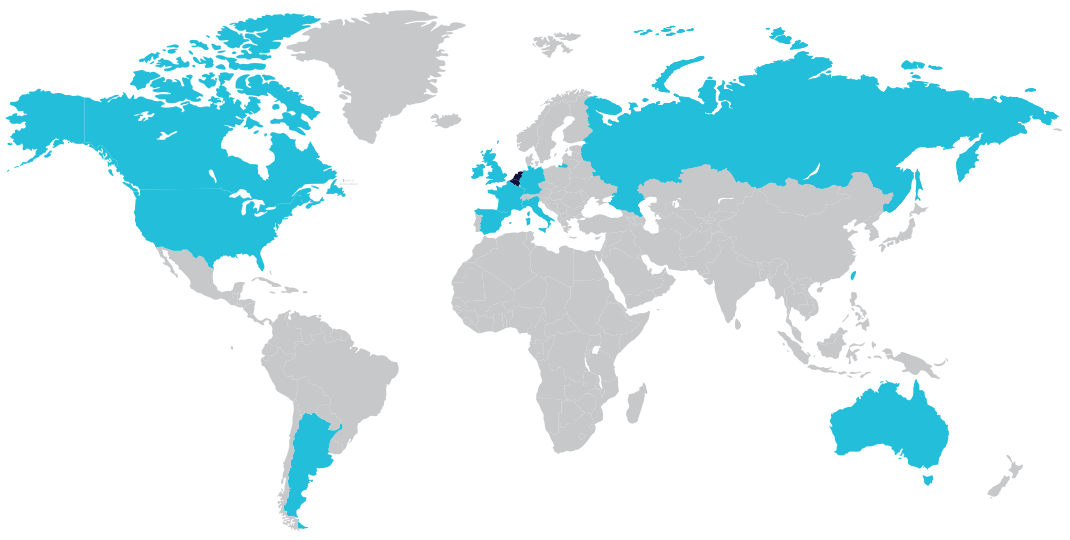
102 participants included to evaluate the change in BMD at **48 weeks** following switch from TDF-containing regimen to DTG + RPV compared to continuing CAR[2]

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.

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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 INI[9]

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