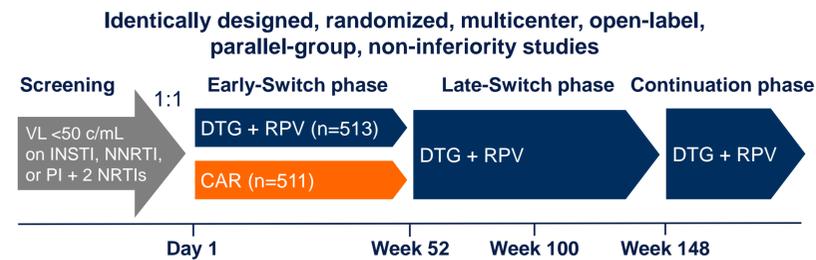


## Introduction

- The SWORD studies demonstrated non-inferiority of switch to dolutegravir (DTG) + rilpivirine (RPV) vs continuing a 3- or 4-drug current antiretroviral regimen (CAR) for 48 weeks and also demonstrated durable suppression to HIV-1 RNA <50 c/mL over 3 years
- The clinical significance of low-level viral load (VL) <50 c/mL remains unclear
- Previous assessment of low-level qualitative HIV-1 RNA using undetectable (Target Not Detected; TND) and detectable (Target Detected; TD) measures showed similar levels of TND for participants receiving DTG + RPV 2-drug regimen (2DR) compared with those who continued their CAR through Week 48<sup>1</sup>
- We present here longer-term HIV-1 RNA data, focusing on low-level qualitative VL data, and including quantitative VL ≥40 c/mL, from the phase III SWORD HIV-1 studies up to Week 148

Figure 1. Study Design



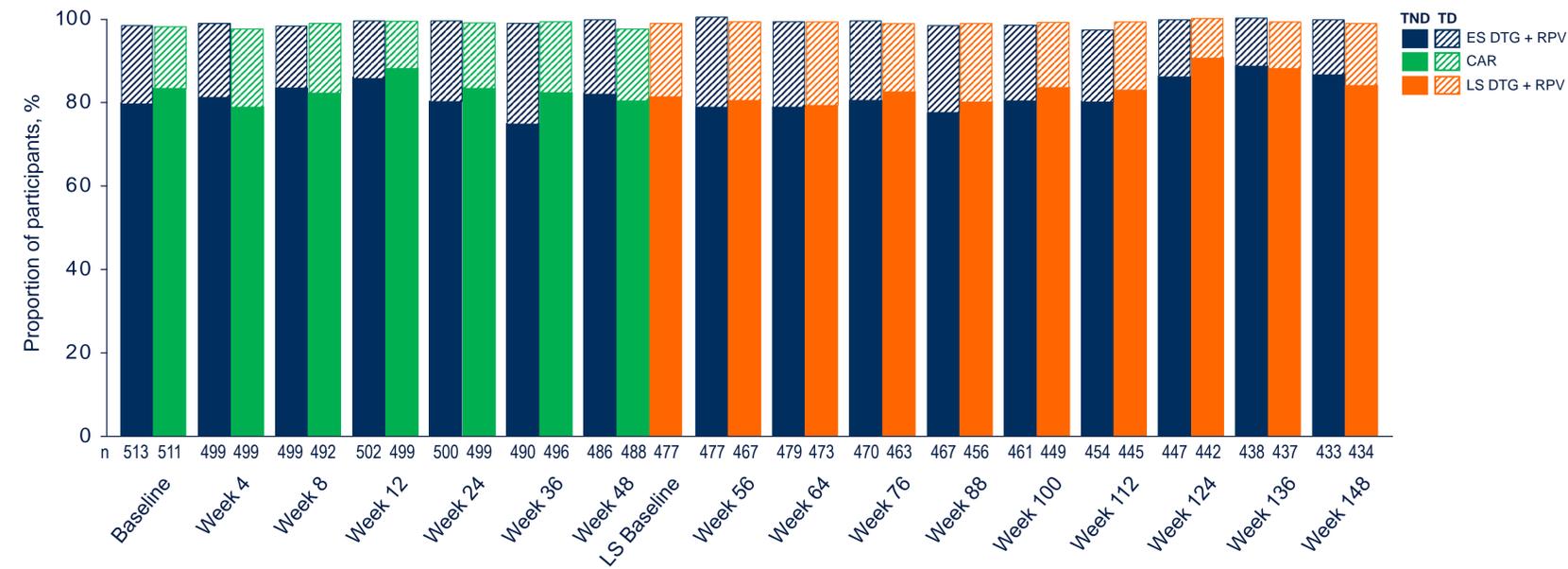
## Methods

- Adults with VL <50 c/mL for ≥6 months were randomized to switch to DTG + RPV (Early-Switch [ES] DTG + RPV group) for 148 weeks or continue CAR. CAR participants with VL <50 c/mL at Week 48 switched at Week 52 (Late-Switch [LS] DTG + RPV group) to receive DTG + RPV for 96 weeks
- The Abbott RealTime assay measures VL quantitatively from 40 c/mL to 10,000,000 c/mL; when VL <40 c/mL it reports qualitative Target Detected (TD) or Target Not Detected (TND) results
- We assessed participants' TND and TD status for those with VL <40 c/mL over time, overall and by Baseline TD or TND status. We also assessed quantitative VLs ≥40 to <50 c/mL, ≥50 to <200 c/mL, and ≥200 c/mL for participants overall
- In "by visit" analyses, the latest VL within each visit is considered. Participants who discontinued from study before reaching a specific timepoint (ie, Week 100, Week 148) are not included in the summaries of the respective timepoint
- Baseline for the LS group is defined as the last VL assessment (usually from the Week 48 visit) before switch to DTG + RPV at Week 52. Per study switch criteria, no participants had VL ≥50 c/mL at LS Baseline

## Results

- 1024 participants were randomized and exposed (ES DTG + RPV, n=513; CAR, n=511) across both studies; 477 CAR participants switched to DTG + RPV at Week 52

Figure 2. Proportion of Participants With TND and TD by Visit Through Week 148 Presented by Arm and Treatment Group



- The proportions of participants with TND were similar through Week 148 across the ES DTG + RPV, CAR, and LS DTG + RPV groups
- Proportions with TND ranged from 75% to 88% for ES DTG + RPV, 79% to 88% for CAR, and 79% to 90% for LS DTG + RPV

Table 1. Proportions of Participants Who Maintained TND at Every Visit by Baseline Category

### A. During 48 Weeks of Treatment

Comparator group <sup>a</sup>	Baseline <sup>b</sup> category		
	Overall	TND	TD
ES DTG + RPV	41% (198/486)	47% (180/383)	19% (18/94)
LS DTG + RPV	48% (215/449)	52% (189/367)	33% (25/76)
CAR	47% (229/488)	53% (215/408)	19% (13/70)

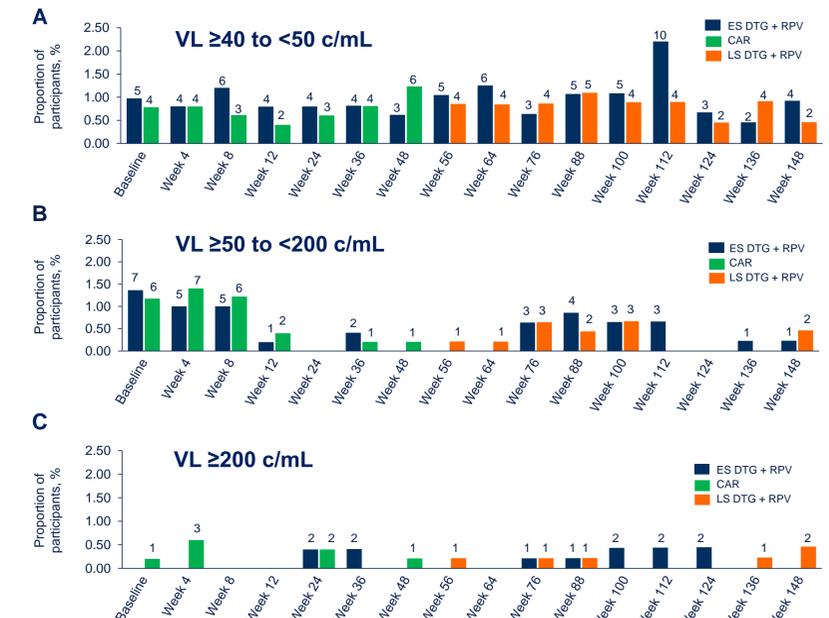
<sup>a</sup>For ES DTG + RPV and CAR, data are through Week 48, and for LS DTG + RPV, data are from Week 52 to Week 100. <sup>b</sup>Baseline is Day 1 for ES DTG + RPV and CAR, and LS Baseline (see Methods) for LS DTG + RPV.

- Similar proportions of participants had TND at all visits through 48 weeks receiving DTG + RPV (in the ES and LS groups) or receiving CAR treatment
- More participants in TND at Baseline category had TND at all visits compared with participants in TD at Baseline category

## Discussion

- Qualitative measures of HIV-1 RNA replication have been noted to correlate with single-copy assay (SCA),<sup>2</sup> and can provide an estimate of viral replication that informs on comparative potency in clinical studies
- The clinical significance and patient management implications of low-level VL measurements have been assessed previously using qualitative data,<sup>3,4</sup> and additional data are needed to inform on this topic

Figure 3. Proportion of Participants With Viral Loads ≥40 c/mL Through Week 148



NOTE: The number of participants in the different categories is shown above the vertical bars at visit weeks. No number indicates there were no occurrences at those visits.

- Numbers and proportions of quantitative VLs ≥40 to <50 c/mL, ≥50 to <200 c/mL, and ≥200 c/mL were low and similar across groups through 148 weeks

## Conclusions

- The proportions of participants with TND by visit under DTG + RPV remained high across all visits, with no decline observed through 148 weeks
- The proportions of participants with TND maintained for all visits were similar across DTG + RPV and CAR groups over 48 weeks of treatment
- The proportions of participants with VL ≥40 c/mL were low and comparable among treatment groups
- This is supportive evidence that long-term treatment with DTG + RPV is efficacious in virologic suppression to <50 c/mL

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