Durable Suppression and Low Rate of Virologic Failure
3 Years After Switch to DTG + RPV 2-Drug Regimen: SWORD-1 and -2 Studies

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Table 1. Confirmed Virologic Withdrawals From Week 100 to Week 148 in Participants Exposed to DTG + RPV

<table>
<thead>
<tr>
<th>Week of</th>
<th>Baseline regimen</th>
<th>INSTI retention</th>
<th>INSTI failure</th>
<th>DTG failure</th>
<th>RPV failure</th>
<th>Week of failure</th>
<th>Resistance mutations</th>
<th>Field change</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>TDF/FTC</td>
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<td>TDF/FTC</td>
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<tr>
<td>148</td>
<td>TDF/FTC</td>
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Methods

Study Design

SWORD-1 and SWORD-2 are identical designed, multicenter, open-label, parallel-group, non-inferiority, phase III studies; participants with baseline HIV-1 RNA <50 c/mL taking INSTI, NNRTI, or PI + 2 NRTIs were randomized 1:1 to switch to DTG + RPV or to continue CAR, those who continued CAR and were suppressed switched to DTG + RPV through Week 148. Data for CAR treatment have been presented elsewhere.1

Study Populations

Participants randomized to continue CAR on Day 1, completed the Early-Switch phase at Week 52, and received at least 1 dose of DTG + RPV upon switching at Week 52 (Late-Switch group).

Results

Overall, 993 participants received DTG + RPV treatment (Early-Switch group, n=513; Late-Switch group, n=480). The majority of AEs were grade 1 or 2. The majority of AEs were grade 1 or 2. Through 148 weeks of treatment, DTG + RPV continued to be efficacious in the Early-Switch group (Figure 1).

Change From Baseline/Late-Switch Baseline in Biomarkers at Week 148

- Decreases in all measured bone turnover biomarkers for both Early-Switch and Late-Switch groups and in retinol-binding protein/creatinine ratio in participants with baseline TDF
- Mean (95% CI) change from baseline was the same in the Late-Switch group
- Only statistically significant decreases occurred in the Early-Switch group
- For participants with baseline TDF

Conclusions

Switching participants from 3DR to the 2DR DTG + RPV was associated with maintenance of viral suppression, low frequency of CVRMs, few observations of INNRTI RAMs, and no INSTI RAMs over treatment for 3 years in the Early-Switch group and over 2 years in the Late-Switch group.

After 148 weeks, DTG + RPV showed a good safety profile with few serious AEs and grade 3 or 4 AEs; biomarker data indicate reduced bone turnover after the switch to DTG + RPV, with significant improvements in renal tubular function for those patients switching from a TDF-containing regimen.

DTG + RPV has demonstrated durable efficacy, is well tolerated, and offers an HIV treatment option with less cumulative ART exposure in select virologically suppressed patients.