Introduction
Abacavir 600 mg/dolutegravir 50 mg/lamivudine 300 mg (ABC/DTG/3TC) fixed-dose combination (Truvada®) is a complete regimen built around DTG, an unboosted integrase inhibitor with a high barrier to resistance

First approval of ABC/DTG/3TC: August 2014 in North America

The STRIIVING study was a 48-week, phase IIb, randomized, open-label, active-controlled, multicenter, parallel-group, noninferiority study conducted at 96 sites in the United States, Puerto Rico, and Canada

Eligibility criteria: ≥18 years of age, HIV-1–positive status, stable ART regimen (ART) at least 2 NRTIs plus either a PI, NNRTI, or INI) for at least 6 months with virological suppression (HIV-1 RNA <50 c/mL), and no serious or fatal AEs related to ART. The study excluded subjects with a CD4 count <100 cells/μL

At baseline, subjects were randomized to receive ABC/DTG/3TC (early switch) or (current ART) (late switch arm) at a 1:1 ratio (n=275 each group) randomized on ABC/DTG/3TC.

The primary endpoint for the STRIIVING study was the proportion of subjects with plasma HIV-1 RNA <50 c/mL at Week 24 using the Snapshot (missing, switch, or discontinuation=failure) algorithm.

Noninferiority margin was set as 10%.

Results
Study Population
Of 841 subjects screened, 553 were randomly assigned (1:1) to receive ABC/DTG/3TC in the early switch group (n=275) or to continue current ART (n=275) in the late switch group (n=275; Figure 1)

The early switch group, 4% of subjects discontinued taking ABC/DTG/3TC between Day 1 and Week 24 due to adverse events (AEs), but no additional subjects discontinued after Week 24

Late switch, 2% of late switch subjects discontinued ABC/DTG/3TC between Week 24 and Week 48

245 of 278 patients (88%) completed the first 24 weeks on current ART; 244 switched to ABC/DTG/3TC at Week 24

Figure 1. Subject Disposition Through 48 Weeks

Early switch group

Late switch group

Table. Adverse Events

<table>
<thead>
<tr>
<th>Event</th>
<th>Early switch</th>
<th>n (%)*</th>
<th>Late switch</th>
<th>n (%)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any AE</td>
<td>180 (66)</td>
<td>205 (75)</td>
<td>146 (56)</td>
<td>156 (57)</td>
</tr>
<tr>
<td>Any drug-related event</td>
<td>57 (21)</td>
<td>62 (22)</td>
<td>32 (13)</td>
<td>31 (11)</td>
</tr>
<tr>
<td>Any serious AE</td>
<td>6 (2)</td>
<td>9 (3)</td>
<td>6 (2)</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Any death</td>
<td>10 (4)</td>
<td>10 (4)</td>
<td>4 (2)</td>
<td>4 (2)</td>
</tr>
</tbody>
</table>

ART: antiretroviral therapy

Efficacy

Through week 24, 85% of subjects were suppressed on ABC/DTG/3TC compared with 73% on current ART (treatment difference 3.6% CI, 1.1% to 2.6%; Figure 2)

83% of subjects in the early switch group were suppressed on ABC/DTG/3TC through Week 48

From Week 24 to Week 48 in the late switch arm, 92% of subjects who switched to ABC/DTG/3TC were suppressed

Conclusions
Efficacy

The virologic response rate was maintained through 48 weeks in the early switch group

In the late switch group, virological suppression was observed in 92% of subjects on ABC/DTG/3TC (24 weeks postswitch)

There were no protocol-defined virologic failures in the study

Tolerability

There were no further discontinuations due to AEs in the early switch arm after Week 24

Low rate of discontinuations in the late-switch arm (2%)

Summary

No data through 48 weeks support switching to ABC/DTG/3TC once daily for subjects with HIV-1 on stable suppressive ART

Acknowledgments: We thank everyone who has contributed to the success of this study, including the following: study participants and their families, the clinical investigators and their staff, and the GSK and ViiV Healthcare study teams. Medical writing support and editorial support was provided by InFlora, Inc and funded by ViiV Healthcare. These data were previously presented at the 21st International AIDS Conference; July 26, 2015; Dallas, Texas, USA. Reference: A, B, C, D, E, F, G, H, I, J, K, L, M, N, O, P, Q, R, S, T, U, V, W, X, Y, Z

2016 Australasian HIV & AIDS Conference; November 16-18, 2016; Adelaide, South Australia