Introduction

- DTG once daily (QD) was well tolerated in ART-naive studies and was shown to have comparable efficacy vs RAL (SPRING-2), and superior efficacy vs DRV (FLAMINGO) and as a regimen with abacavir/lamivudine (ABC/3TC) QD vs Atripla® (EFV/TDF/FTC) QD (SINGLE).3
- Analysis of 96-week safety and efficacy data by age, race and gender subgroups were evaluated

Methods

- SPRING-2 randomized subjects to DTG 50 mg QD or RAL 400 mg twice daily; FLAMINGO randomized subjects to DTG 50 mg or DRV QD with investigator-selected NRTIs (TDF/FTC or ABC/3TC).
- SINGLE randomized subjects to DTG 50 mg + ABC/3TC QD or EFV/TDF/FTC QD.
- Response rates by FDA snapshot at 96 weeks and adverse events (AEs) were summarized in subgroups (< vs ≥50 years), race (white vs non-white) and gender (male vs female).

Results

- DTG efficacy rates at 96 weeks remained high across subgroups (Figures 1-3).
- The efficacy of DTG QD was higher or comparable to comparator agents in subjects aged <50 years old, but not in the smaller cohort of subjects ≥50 years old.
- Safety summaries showed comparable grade 2 to 4 drug-related AEs (Figure 5A) across subgroups and low rates of AEs leading to withdrawals across all DTG subgroups (Figure 5B).

Figure 1. Snapshot Efficacy at Week 96 by Subgroup4

Figure 2. Snapshot by Visit: Subjects With Baseline CD4 Count <200 cells/mm³

Figure 3. Snapshot by Visit: Subjects With Baseline VL >100,000 copies/mL

Figure 4. Snapshot by Visit: Subjects Receiving ABC/3TC NRTI Backbone

Figure 5. Adverse Events by Subgroup. (A) Grade 2 to 4 Drug Related Events. (B) Adverse Events Leading to Withdrawal

Table 1. Number of Patients in Each Subgroup

<table>
<thead>
<tr>
<th></th>
<th>SPRING-2</th>
<th>SINGLE</th>
<th>FLAMINGO</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTG</td>
<td>RAL</td>
<td>DRV</td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>411</td>
<td>411</td>
<td>419</td>
</tr>
<tr>
<td>Age &lt;50 years</td>
<td>370</td>
<td>365</td>
<td>361</td>
</tr>
<tr>
<td>Age ≥50 years</td>
<td>41</td>
<td>46</td>
<td>53</td>
</tr>
<tr>
<td>White</td>
<td>346</td>
<td>352</td>
<td>284</td>
</tr>
<tr>
<td>Non-white</td>
<td>65</td>
<td>59</td>
<td>130</td>
</tr>
<tr>
<td>Male</td>
<td>348</td>
<td>355</td>
<td>347</td>
</tr>
<tr>
<td>Female</td>
<td>63</td>
<td>56</td>
<td>67</td>
</tr>
</tbody>
</table>

*DTG treatment with abacavir/lamivudine (ABC/3TC) or EFV/TDF/FTC.

Conclusions

- In the 3 treatment-naïve clinical trials, DTG QD was seen to be a consistently effective and well-tolerated treatment option across age, race and gender subgroups.
- DTG efficacy was maintained in subjects with CD4 <200 cells/mm³.
- Some numerical variability among the subgroups is likely explained by small sample sizes.

Acknowledgments: The authors thank all of the subjects who participated in SPRING-2, SINGLE, and FLAMINGO; all of the investigators and site staff; the study monitors, and the numerous contributors from ViiV Healthcare and GlaxoSmithKline.