Efficacy and Safety of Dolutegravir/Lamivudine (DTG/3TC) in Black and Asian Participants From TANGO and SALSA: Pooled 48-Week Data Analyzed by Race

Princy Kumar,1,2 Debbie Hagins,1,3 Jaime Federico Andrade-Villanueva,1 Po-Liang Lu,1 Eisuke Adachi,4 Rabelio Ruth,5 Thomas Luis,6 Mourir Al-Khaled,7 Richard Grove,8 Brian Wynne,9,10 Bryn Jones,9 and Chihiro Okoli11

1Georgetown University Medical Center, Washington, DC, USA; 2Georgia Department of Public Health, Coastal Health District, Chatham CARE Center, Savannah, GA, USA; 3Hospital Civil ‘Fray Antonio Alcalde’; Guadalajara, Mexico; 4Department of Hepatology, Tokyo Women’s Medical University, Tokyo, Japan; 5Hospital Universitario 12 de Octubre, Madrid, Spain; 6Reinshof Klinik, Schwerin, Germany; 7VIV Healthcare, Brentford, UK; 8GSK, Brentford, UK; 9VIV Healthcare, Durbuy, NC, USA

Key Takeaways
- The efficacy and safety of switching to the 2-drug regimen dolutegravir/lamivudine (DTG/3TC) was analyzed by race using data from the pooled TANGO and SALSA trials.
- Globally, Black populations represent the highest proportion of people living with HIV, however, across different races and ethnic groups, including Asian populations, they are often underrepresented in HIV clinical trials, despite recent efforts to increase their participation.
- Proportions of adverse events (AEs) were similar between treatment groups overall and across racial groups.
- Withdrawals due to AEs were low and consistent across race subgroups.

Introduction
- International guidelines recommend the 2-drug regimen DTG/3TC as a switch option with high efficacy and good safety and tolerability in HIV-infected patients.

Methods
- Week 48 (primary endpoint) data from the Phase 3 TANGO and SALSA trials evaluating switch to once-daily DTG/3TC fixed-dose combination in HIV-infected patients on antiretroviral regimens (CAR) were analyzed (Figure 1).
- Proportions of participants with HIV-1 RNA <50 copies/mL, (Snapshot, ITT-E) were analyzed across race subgroups.
- Adjusted mean change from baseline in CD4+ cell count and CD4+/CD8+ ratio was analyzed using mixed-models repeated measures analyses.

Results
- Participants: Of 1,234 participants (DTG/3TC, n=615; CAR, n=619), 878 (71%) identified as White, 202 (16%) as Black, 91 (8%) as Asian, and 58 (5%) as other races (Table 1).
- Across races, CD4+/CD8+ ratio was maintained from baseline (0.9–1.5, Table 2).
- Across race subgroups, no significant differences were observed in safety and tolerability parameters.

Safety
- Proportions of adverse events (AEs) were similar between treatment groups overall and across races.
- Withdrawals due to AEs were low and consistent across race subgroups.

Figure 1. Study Design

Figure 2. Proportion of Participants With HIV-1 RNA <50 copies/mL at Week 48 and Overall by Race: TANGO and SALSA Pooled ITT-E Population

Table 1. Selected Demographics and Baseline Characteristics

Table 2. Adjusted Mean Change From Baseline to Week 48 in CD4+ Cell Count and CD4+/CD8+ Ratio by Race: TANGO and SALSA Pooled ITT-E Population

Conclusions
- Switching to DTG/3TC resulted in high rates of maintained virologically suppression, a high barrier to resistance, and good tolerability across races, including among people living with HIV identifying as Black or Asian.

Figure 3. Adjusted Mean Change From Baseline to Week 48 in Fasting Lipids (Log-Transformed) Overall and in Participants Who Identified as Black or Asian: TANGO and SALSA Pooled Safety Population

*Includes African American, Asian American, Pacific Islander, and individuals of multiple races (DTG/3TC - CAR).

**No participants met confirmed virologic withdrawal (CVW) criteria in the DTG/3TC group: 1 participant who identified as Black, met CVW criteria in the CAR group, and no resistance was detected.

References: