CHANGES IN INFLAMMATORY BIOMARKERS AND BASELINE VARIABLES AFTER SWITCHING TO DOLUTEGRAVIR/LAMIVUDINE (DTG/3TC) IN 2 RANDOMIZED CLINICAL TRIALS OF VIROLOGICALLY SUPPRESSED ADULTS: 48-WEEK POOLED ANALYSIS

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Background: Persistent inflammation has been linked to increased risk of non–AIDS-related comorbidities in people with HIV-1. International guidelines recommend the 2-drug regimen dolutegravir/lamivudine (DTG/3TC) as a switch option, supported by randomized clinical trials demonstrating its durable efficacy and high barrier to resistance. We present inflammatory biomarker results in virologically suppressed adults switching to DTG/3TC.

Methods: This analysis included 48-week pooled data from the phase 3 TANGO and SALSA trials of adults with HIV-1 RNA <50 c/mL randomized to switch to once-daily DTG/3TC fixed-dose combination or continue current antiretroviral regimen (CAR). Using a multivariate analysis of covariance model adjusting for relevant baseline variables, log-transformed Week 48 serum inflammatory biomarker levels and CD4+/CD8+ ratio were compared between groups and associations with baseline variables evaluated as fixed effects.

Results: Week 48 levels of soluble CD14 (sCD14) and C-reactive protein (CRP) appeared lower in the DTG/3TC vs CAR groups, and for sCD163, IL-6, and CD4+/CD8+ ratio, Week 48 values were similar between groups. Across biomarkers, higher baseline values were strongly associated with higher Week 48 levels. Female participants had higher Week 48 levels of all inflammatory biomarkers compared with male participants. Asian participants appeared to have lower Week 48 levels compared with other races across all inflammatory biomarkers, although sample sizes were small. Increasing age appeared to be associated with higher sCD14, sCD163, and IL-6 levels but not with CRP and CD4+/CD8+ ratio. Higher IL-6 and CRP levels at Week 48 were observed in participants with obese body mass index at baseline.

Conclusion: At Week 48 in this pooled analysis of 2 randomized trials, inflammatory biomarker levels were similar between the 2-drug regimen DTG/3TC and a broad range of 3-/4-drug regimens. Multiple baseline variables besides antiretroviral therapy were associated with each inflammatory biomarker. These data highlight the multifactorial aspect of the inflammatory response.

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