

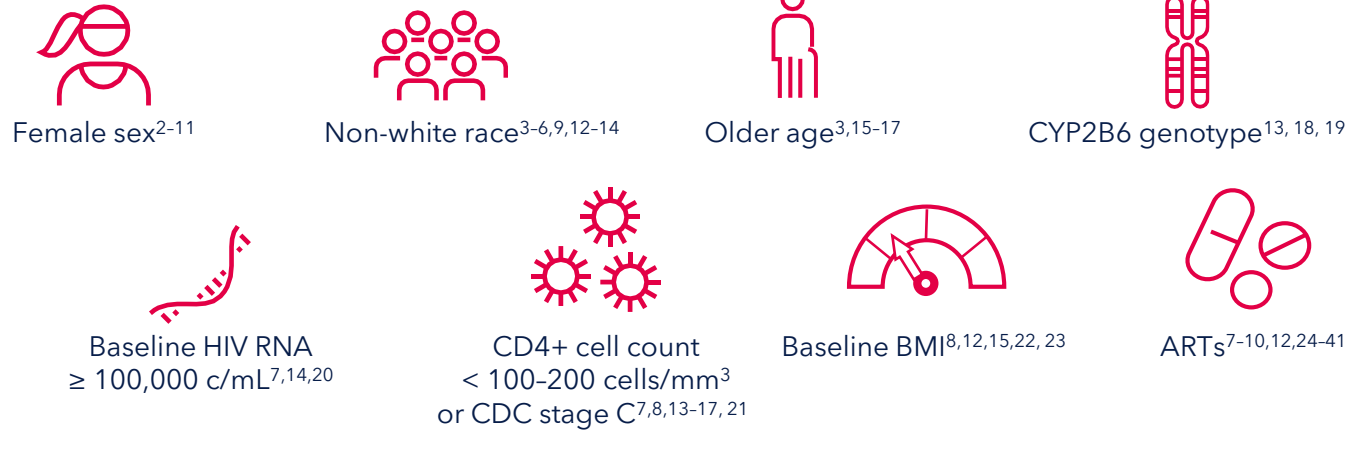
Weight Changes in Patients Receiving Dolutegravir-Based Regimens

Weight Gain in DHHS Guidelines

ART-associated Weight Gain¹

- Significant weight gain may occur with all ART regimens, but it appears to be more pronounced with DTG, BIC, or TAF
- The mechanism of weight gain is unclear and under investigation

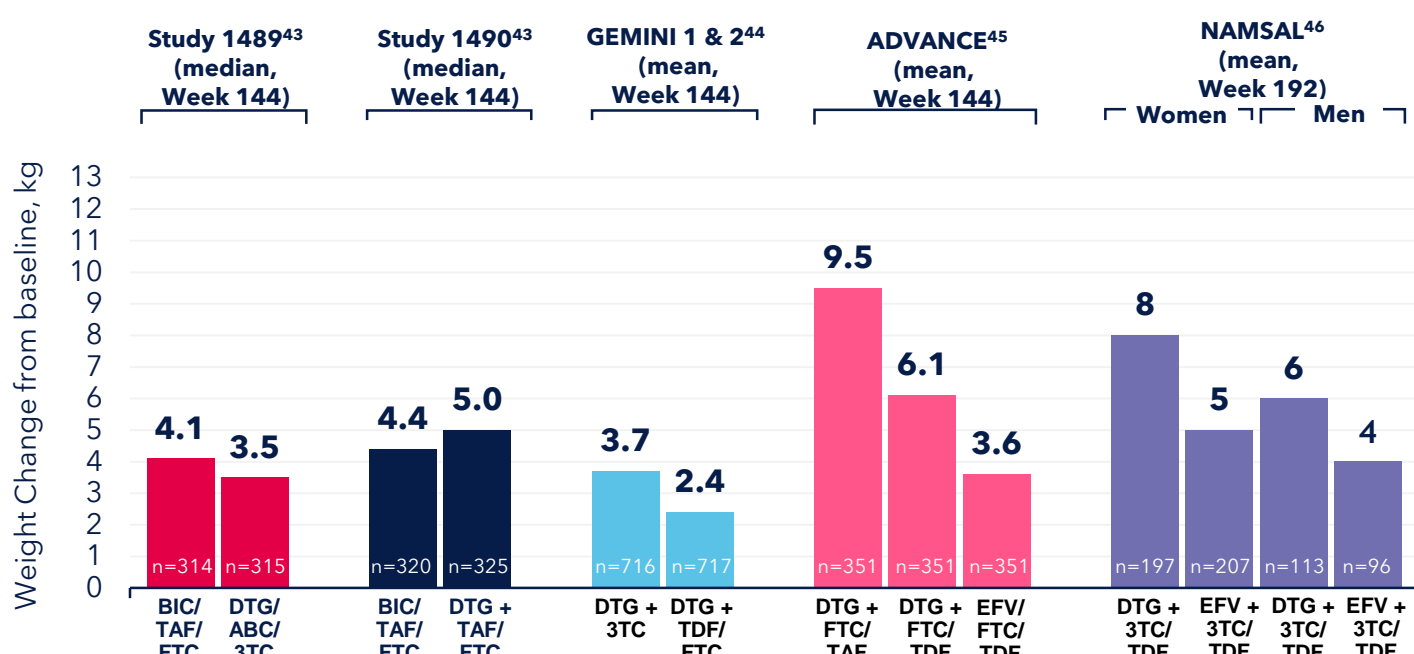
Risk Factors for Weight Gain in PLHIV



Mean Weight Gain in PLHIV

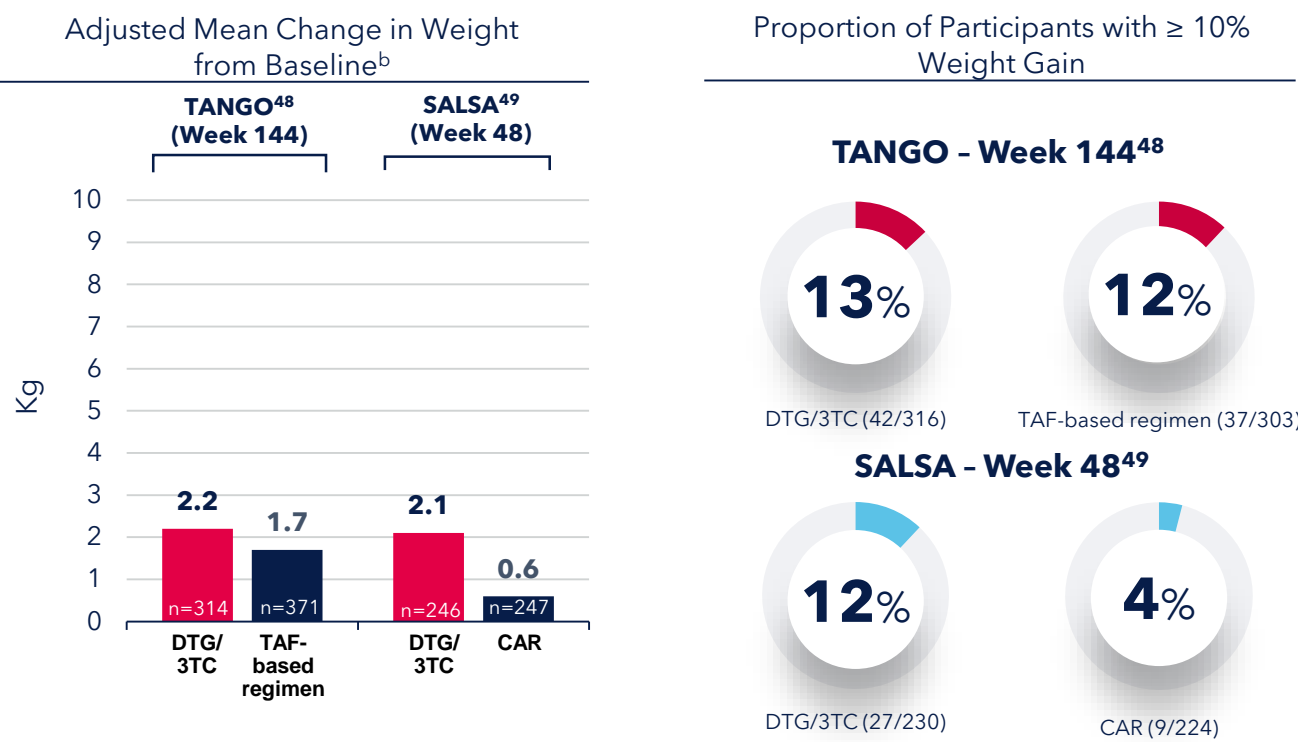
A mean increase in weight ranging from 0.8 to 9.5 kgs has been observed in participants receiving a DTG-based regimen across 1 phase 2b and 7 Phase 3 treatment naïve clinical trials and 2 Phase 3 treatment experienced clinical trials.⁴²⁻⁴⁹

Weight Change in Phase 3 Treatment Naïve Adult Clinical Trials



- ARIA also was a Phase 3 study in women with HIV-1 taking DTG/ABC/3TC. Adjusted mean change in weight^a from baseline to Week 48 for the DTG (n =248) vs ATV/r (n = 247) group was 2.61 vs 1.41 kg.⁴⁷

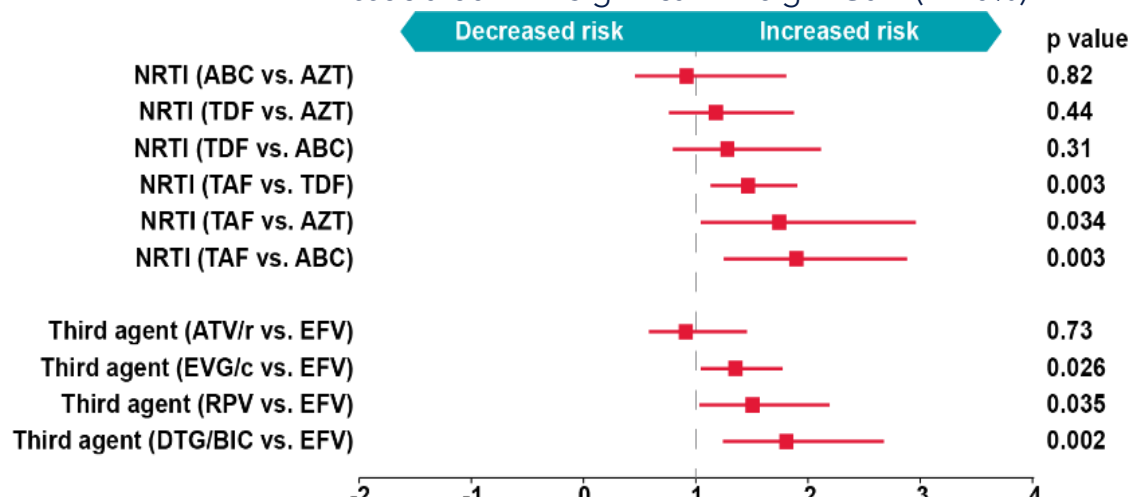
Phase 3 Treatment Experienced Adult Clinical Trial Results



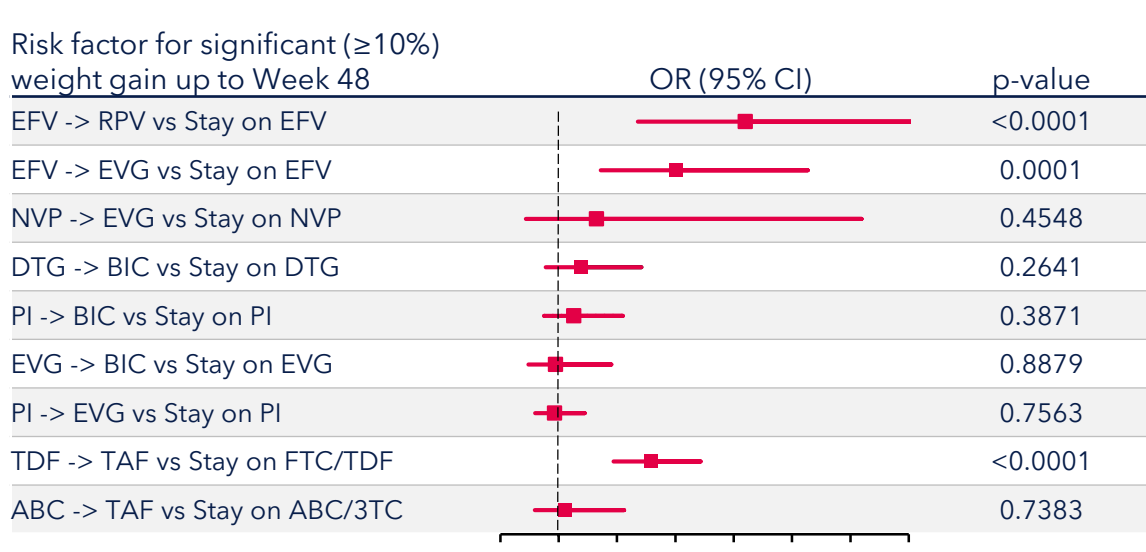
Risk Factors for Weight Gain After Initiation of ART or after ART switch

Pooled data from 8 randomized clinical trials was assessed in over 5,000 treatment naïve patients to identify risk factors for weight gain after the initiation of ART. INSTIs were associated with more weight gain than PIs or NNRTIs, with DTG and BIC being associated with more weight gain than EVG/c.³²

ART Associated with Significant Weight Gain ($\geq 10\%$)



Pooled data from 12 trials was assessed in over 7,000 PLHIV on ART and virologically suppressed for a minimum of 12 months. In a logistic regression model also including ART switch categories, there was increased risk for $\geq 10\%$ weight gain with switch from EFV to RPV or to EVG/c and switch from TDF to TAF.²²



PI

Important safety information is found in the Prescribing Information.

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FOOTNOTES: ^a The mixed-model repeated measure included fixed effects terms for treatment, visit, screening plasma HIV-1 RNA (continuous), screening CD4+ cell count (continuous), race (African American/African heritage, other), and interaction of visit by treatment and the treatment and the corresponding baseline weight value as a fixed effect covariant. ^b The mixed-model repeated measures adjusting for treatment, visit, baseline third agent class, CD4+ cell count (continuous), age (continuous), sex, race, prior TAF duration (continuous), region, BMI subgroup, treatment-by-visit interaction, treatment-by-BMI subgroup interaction, BMI subgroup-by-visit interaction, and treatment-by-BMI subgroup-by-visit interaction, with visit as the repeated factor.

ABBREVIATIONS: 3TC = lamivudine; ABC = abacavir; ART = antiretroviral; BIC = bictegravir; CAR = combination antiretroviral therapy; DHHS = Department of Health and Human Services; DTG = dolutegravir; EFV = efavirenz; FTC = emtricitabine; OR = odds ratio; PLHIV = people living with HIV; TAF = tenofovir alafenamide.

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