

CO-01. NON-INFERIOR EFFICACY AND LESS WEIGHT GAIN WHEN SWITCHING TO DTG/3TC THAN WHEN SWITCHING TO BIC/FTC/TAF IN VIROLOGICALLY SUPPRESSED PEOPLE WITH HIV: PASODOBLE (GESIDA_11720) RANDOMIZED CLINICAL-TRIAL

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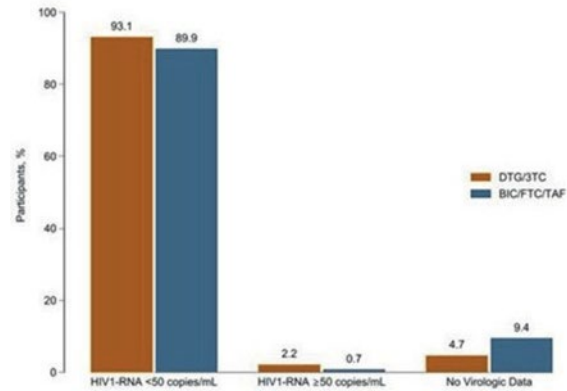
Introduction: DTG/3TC and BIC/FTC/TAF are preferred regimens in major guidelines, but there are no fully powered trials comparing between them.

Methods: PASO-DOBLE (ClinicalTrials.gov NCT04884139) is a randomized, open-label trial conducted at 30 sites throughout Spain. Virologically suppressed PWH on regimens containing ≥ 1 pill/day, boosters, or drugs with cumulative toxicity such as efavirenz or TDF were eligible. Participants were randomized (1:1) to switch stratifying by TAF in the regimen discontinued and sex. Primary endpoint was the proportion of PWH with RNA ≥ 50 copies/mL at 48 weeks (FDA snapshot, 4% non-inferiority margin) in the exposed intention-to-treat population. Weight changes were also evaluated.

Results: Between 14-July-2021 and 24-March-2023, 553 PWH initiated DTG/3TC (n = 277) or BIC/FTC/TAF (n = 276), including 155 (28%) with TAF in the regimen discontinued and 147 (27%) women. At 48 weeks, DTG/3TC was non-inferior to BIC/FTC/TAF [risk difference between DTG/3TC (2.2%) minus BIC/FTC/TAF (0.7%) 1.4%, 95%CI -0.5 to 3.4] (Fig. A). HIV RNA levels were low (≤ 282 copies/mL) in those showing detectable viral load. Mean adjusted weight increased significantly more with BIC/FTC/TAF (1.81 kg, 95%CI 1.28-2.34) than with DTG/3TC (0.89 kg, 95%CI 0.37-1.41) [difference 0.92 kg, 95%CI 0.17-1.66]. The proportion of participants with weight gain > 5% at 48 weeks was 29.9% for BIC/FTC/TAF vs. 20% for DTG/3TC (adjusted OR 1.81, 95%CI 1.19-2.76). While proportions of PWH experiencing > 5% weight gain with DTG/3TC were similar irrespective of the nucleos(t)ide reverse transcriptase inhibitor (NRTI) backbone discontinued, proportions of PWH experiencing > 5% weight gain with BIC/FTC/TAF were 50% or 100% higher than those with DTG/3TC when switching from abacavir or TDF (Figure B). Weight change in women (OR 1.131, 95%CI: 0.700- 1.826) didn't differ from that in men. There were few discontinuations (DTG/3TC=1, 0.4%; BIC/FTC/TAF = 2, 0.7%) due to adverse events.

Conclusions: Switching to DTG/3TC demonstrated non-inferior efficacy and resulted in less weight gain than switching to BIC/FTC/TAF at 48 weeks.

A) Snapshot Outcomes at Week 48 in the ITT-E Population



B) Weight gain >5% stratified by NRTI at baseline

