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SWITCH TO BICTEGRAVIR/F/TAF FROM DTG AND ABC/3TC
Clinical: (H) Antiretroviral Therapy: Efficacy and Effectiveness Studies
Authors: Jean-Michel Molina1, Douglas Ward2, Indira Brar3, Anthony Mills4, Hans-Jurgen Stellbrink5, Luis López-Cortés6, Peter Ruane7, Daniel Podzamczer8, Cynthia Brinson9, Joseph M. Custodio10, Hui Liu10, Kristen Andreatta10, Hal Martin10, Andrew Cheng10, Erin Quirk10
Institutions: 1St. Louis Hospital, Paris, France, 2Dupont Circle Physicians Group, Washington, DC, USA, 3Henry Ford Hospital, Detroit, MI, USA, 4Southern California Men's Medical Group, Los Angeles, CA, USA, 5ICH Study Center, Hamburg, Germany, 6Hospital Universitario Virgen del Rocio, Sevilla, Spain, 7Peter J Ruane, MD Inc, Los Angeles, CA, USA, 8Hospital Universitario de Bellvitge, Barcelona, Spain, 9Central Texas Clinical Research, Austin, TX, USA, 10Gilead Sciences, Inc, Foster City, CA, USA
Presenting Author: *Jean-Michel Molina, MD, PhD*
Background: Bictegravir, a novel, unboosted INSTI with a high barrier to resistance and low potential for drug interactions, has been coformulated with the recommended NRTI backbone of emtricitabine and tenofovir alafenamide (B/F/TAF) as a fixed-dose combination (FDC). We report the primary Week (W) 48 efficacy and safety Phase 3 results of switching to B/F/TAF from dolutegravir plus abacavir/lamivudine (DTG+ABC/3TC) or FDC of DTG/ABC/3TC.
Methods: HIV-infected adults virologically suppressed on DTG/ABC/3TC or DTG plus ABC/3TC (DTG/ABC/3TC group), with estimated glomerular filtration rate (eGFR) ≥50 mL/min were randomized 1:1 to switch to B/F/TAF (50/200/25 mg) once daily or continue current regimen as DTG/ABC/3TC through week 48 in a double-blinded fashion. Primary endpoint was proportion with HIV-1 RNA ≥50 copies/mL (c/mL) at W48 (FDA snapshot). Noninferiority was assessed through 95.002% confidence intervals (CI) using a margin of 4%. Secondary endpoints were proportion with HIV-1 RNA <50 copies/mL and safety (adverse events [AEs], laboratory results, bone mineral density [BMD], and renal biomarkers).
Results: 563 participants were randomized and treated (B/F/TAF n=282, DTG/ABC/3TC n=281): 11% women, 22% Black, median age 46 yrs (range 20-71). At W48, 1.1% switching to B/F/TAF and 0.4% continuing DTG/ABC/3TC had HIV-1 RNA ≥50 c/mL (difference 0.7%; 95%CI -1.0% to 2.8%, p=0.62), demonstrating noninferiority. At W48, proportion with HIV-1 RNA <50 c/mL was 93.6% on B/F/TAF and 95.0% on DTG/ABC/3TC. No participant developed resistance to any study drug. The most common AEs were upper respiratory tract infection (10% B/F/TAF, 10% DTG/ABC/3TC), diarrhea (9%, 5%), nasopharyngitis (7%, 8%) and headache (7%, 7%). Few participants (6 [2%], 2 [1%]) had AEs leading to premature study drug discontinuation. Mean BMD increased similarly in both groups. Percentage changes from baseline in renal biomarkers were similar between treatment groups (Table). Lipid parameters were similar between groups with the exception of a small decrease in triglycerides seen in the B/F/TAF group.
Conclusion: Switching to B/F/TAF was noninferior to continuing DTG/ABC/3TC with low rates of W48 virologic failure, high rates of maintained virologic suppression, and no resistance. B/F/TAF was well tolerated, with a similar bone and urine protein safety profile to DTG/ABC/3TC.