PHASE 3 RANDOMISED, CONTROLLED TRIAL OF SWITCHING TO FIXED-DOSE BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (B/F/TAF) FROM BOOSTED PROTEASE INHIBITOR-BASED REGIMENS IN VIROLOGICALLY SUPPRESSED ADULTS: WEEK 48 RESULTS

Authors:
Daar ES1, DeJesus E2, Ruane P3, Crofoot G4, Creticos C5, Molina J-M6, Koenig E7, Liu Y-P8, Andreatta K8, Graham H8, Cheng A8, Martin H8, Baker D9, Quirk E8

1Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Torrance, CA, USA, 2Orlando Immunology Center, Orlando, FL, USA, 3Ruane Clinical Research Group, Los Angeles, CA, USA, 4The Crofoot Research Center, Houston, TX, USA, 5Howard Brown Health Center, Chicago, IL, USA, 6Saint-Louis Hospital, Paris, France, Medicine, 7Instituto Dominicano de Estudios Virologicos, Santo Domingo, Dominican Republic, 8Gilead Sciences, Foster City, CA, USA, 9East Sydney Doctors, Sydney, NSW, Australia

Background:
Bictegravir (B), a novel, potent integrase strand transfer inhibitor with a high barrier to resistance and low potential for drug-drug interactions, was coformulated with the recommended nucleoside reverse transcriptase inhibitor backbone emtricitabine (FTC)/tenofovir alafenamide (F/TAF) and demonstrated high efficacy and tolerability in randomised studies in treatment-naive adults. This randomised Phase 3 study assesses efficacy and safety of switching to B/F/TAF from a multi-tablet regimen containing a boosted protease inhibitor (bPI).

Methods:
HIV-infected adults suppressed on regimens of boosted atazanavir (ATV) or darunavir (DRV) + abacavir/lamivudine (ABC/3TC) or FTC/tenofovir disoproxil fumarate (TDF), were randomised 1:1 to continue their current bPI regimen or switch to open-label coformulated B/F/TAF (50/200/25 mg) once daily. 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 included proportion with HIV-1 RNA <50 c/mL and safety measures at W48.

Results:
577 participants were randomised and treated with B/F/TAF (n=290) or current bPI regimens (n=287): 17% women, 26% Black, median age 48 yrs. Most were receiving a bPI with FTC/TDF (85%) at screening. At W48, switching to B/F/TAF was noninferior to continuing bPI with 1.7% in each group having HIV-1 RNA ≥50 copies/mL (difference -0.0%; 95.002%CI -2.5% to 2.5%, p=1.00); the proportion with HIV-1 RNA <50 c/mL was 92.1% in B/F/TAF vs 88.9% in bPI. No participant on B/F/TAF developed resistance to study drugs. One participant on DRV/ritonavir + ABC/3TC developed a treatment-emergent L74V mutation. Incidence of grade 3 or 4 AEs was similar (B/F/TAF 4%, bPI regimens 6%). No renal discontinuations or tubulopathy cases occurred with B/F/TAF.

Conclusion:
Adults switching to B/F/TAF from a boosted PI maintained high rates of virologic suppression without resistance. B/F/TAF was safe and well tolerated.

Disclosure of Interest Statement:
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