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

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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-naïve 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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