B/F/TAF five-year outcomes in treatment-naïve adults

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Background: Bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) is a recommended regimen for people with HIV-1 (PWH). We present 5-year outcomes of two phase 3 studies of B/F/TAF in treatment-naïve PWH.

Methods: We conducted 2 randomized, double-blind, phase 3 studies of B/F/TAF in treatment-naïve adults – Study 1489 (1489): B/F/TAF vs DTG/ABC/3TC and Study 1490 (1490): B/F/TAF vs DTG+F/TAF. After 144W, participants were offered continuation of B/F/TAF for 96W in open-label extensions (OLEs).
Efficacy was assessed as proportion with HIV-1 RNA <50 copies/mL at each visit using missing=excluded analysis; safety by adverse events (AEs) and laboratory results. Bone mineral density (BMD) was measured in those randomized to B/F/TAF in 1489. We present cumulative results for participants treated with B/F/TAF in randomized and/or OLE phases through a maximum of 240W.

Results: 314 participants in 1489 and 320 in 1490 randomized to B/F/TAF, 252 and 254 enrolled in OLE, respectively. 315 randomized to DTG/ABC/3TC in 1489 and 325 randomized to DTG+F/TAF in 1490 and 254 and 265 enrolled in OLE, respectively. Efficacy was >98% after W48 at each visit through W240 in both studies. No resistance to components of B/F/TAF was detected in the resistance analysis population. During the OLE, 6/504 B/F/TAF participants experienced an AE that led to drug discontinuation, none were renal; ≤1.6% had a Grade 3 or 4 drug-related AE. Small median changes in eGFR and stable TC:HDL were observed through W240 in all arms. Median change in weight from BL to W240 was 6.1kg in B/F/TAF participants; median weight change for comparators at W144: 3.5kg (1489) and 5.0kg (1490), with 2.4kg and 1.3kg additional gains observed between W144 to W240, respectively. Mean % changes (SD) in hip and spine BMD through W240 in B/F/TAF participants were -0.29%(5.29) and -0.23%(5.16), respectively.

Conclusion: Over 5 years of follow up in treatment naïve PWH, B/F/TAF was well tolerated and highly efficacious. These results confirm long term safety and efficacy of B/F/TAF.

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