Long-term efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in ART-naïve adults

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Background:
To evaluate efficacy and safety of bictegravir, emtricitabine, and tenofovir alafenamide (B/F/TAF) and dolutegravir (DTG)-containing regimens through 144 weeks(W).

Methods:
We conducted two randomized, double-blind, active-controlled phase 3 studies of B/F/TAF in treatment-naïve adults with HIV. Study 1489 randomized HLA-B*5701-negative adults without HBV to receive B/F/TAF or DTG, abacavir, and lamivudine (DTG/ABC/3TC). Study 1490 randomized adults to B/F/TAF or DTG+F/TAF. Participants were pooled into three groups: B/F/TAF (Studies 1489, 1490), DTG/ABC/3TC (Study 1489), and DTG+F/TAF (Study 1490). A pre-specified pooled analysis at W144 assessed efficacy as the proportion with HIV-1 RNA <50 c/mL and safety; proteinuria and bone mineral density (BMD) were measured in 1489 only.

Results:
1274 adults were randomized/treated (634 B/F/TAF, 315 DTG/ABC/3TC, 325 DTG+F/TAF). Baseline characteristics were similar across groups. At W144, 82% on B/F/TAF, 84% on DTG/ABC/3TC, and 84% on DTG+F/TAF achieved HIV-1 RNA <50 c/mL. No participant developed treatment-emergent resistance to any study drug. The proportion with drug-related adverse events (AEs) was 26% (B/F/TAF), 42% (DTG/ABC/3TC), and 29% (DTG+F/TAF). AEs led to discontinuation for 1% (B/F/TAF), 2% (DTG/ABC/3TC), and 2% (DTG+F/TAF). Changes in eGFR at W144 were similar across groups. In Study 1489 changes in proteinuria and renal biomarkers and mean percentage change from baseline in hip and spine BMD at W144 were similar. Small differences from baseline in fasting LDL, HDL, and TC:HDL were observed with B/F/TAF vs DTG/ABC/3TC but not vs DTG+F/TAF.

Conclusion:
In ART-naïve adults, use of B/F/TAF resulted in high rates of virologic suppression through W144. B/F/TAF was well tolerated, had fewer drug-related AEs compared with

DTG/ABC/3TC, and no clinically relevant effect on bone and renal safety or fasting lipids.

Disclosure

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