FACTORS ASSOCIATED WITH HBV RESPONSE TO B/F/TAF VS. DTG + F/TDF AT W96 IN PEOPLE WITH HIV-1 AND HBV

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Background:
The Phase 3 ALLIANCE study investigated the efficacy and safety of bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) vs. dolutegravir + emtricitabine/tenofovir disoproxil fumarate (DTG+F/TDF) in people initiating therapy for HIV-1 and HBV. Over 96 weeks (W), B/F/TAF showed significantly higher rates of HBeAg loss/seroconversion, numerically higher rates of HBsAg loss/seroconversion and ALT normalization, vs. DTG+F/TDF. Overall, rates of HBeAg, HBsAg loss/seroconversion and ALT normalization were substantially higher in ALLIANCE than in TDF or TAF studies for HBV monoinfection, but the mechanism behind this difference is unclear. We explore factors associated with HBV treatment response with B/F/TAF vs. DTG+F/TDF through W96.

Methods:
Adults with HIV-1/HBV from 46 sites (N=243) were randomized 1:1 to B/F/TAF or DTG+F/TDF plus corresponding placebos. This subgroup analysis compares the percentages of participants with HBe/sAg loss/seroconversion or ALT normalization with B/F/TAF vs. DTG+F/TDF at W96 according to baseline demographics, HBV genotype, and markers of HIV-1/HBV disease severity.

Results:
There were significantly higher rates of HBeAg loss/seroconversion with B/F/TAF vs. DTG+F/TDF in participants who were <30 years, or with baseline HBV DNA <8 $\log_{10}$IU/mL, HBV genotype B/C, or baseline ALT levels above normal , and in Asians, or with ≥95% study drug adherence, baseline HIV-1 RNA ≤100,000 c/mL, baseline CD4 ≥200 cells/μL at baseline. There were also significantly higher rates with B/F/TAF vs. DTG+F/TDF for: HBsAg loss/seroconversion in participants with HBV genotype B/C; HBsAg loss and ALT normalization in those with baseline HBV DNA <8 $\log_{10}$ IU/mL; HBsAg loss in those who were Asian or who had ≥95% study drug adherence; ALT normalization in those who were HBeAg-negative at baseline.

Conclusions:
At 96W, B/F/TAF was associated with significantly higher rates of HBeAg loss/seroconversion and numerically higher rates of HBsAg loss/seroconversion and

ALT normalization compared with DTG+F/TDF in people with HIV-1/HBV. This analysis suggests that the treatment difference of TAF- vs. TDF-based therapy for some or all HBV treatment outcomes may be greater for certain subgroups.

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