

144 WEEK EFFICACY AND SAFETY OF B/F/TAF IN TREATMENT-NAÏVE ADULTS ≥50 YRS

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Background:

As people with HIV age, identifying effective and safe regimens is of heightened importance. Bictegravir, emtricitabine, tenofovir alafenamide (B/F/TAF) may benefit older adults due to its favorable adverse event (AE) profile and few drug interactions.

Methods:

We conducted two randomized, double blind, phase 3 studies of B/F/TAF in treatment-naïve adults, Studies 1489: B/F/TAF vs dolutegravir, abacavir, lamivudine (DTG/ABC/3TC) and 1490: B/F/TAF vs DTG+F/TAF. A pooled analysis assessed efficacy (proportion HIV-1 RNA <50c/mL) and safety at Week (W)144 in adults ≥50 and <50 yrs. Proteinuria and bone mineral density (BMD) were measured in Study 1489 only.

Results:

1274 were randomized and treated (634 B/F/TAF, 315 DTG/ABC/3TC, 325 DTG + F/TAF); 196 were ≥50 yrs (96 B/F/TAF, 41 DTG/ABC/3TC, 59 DTG + F/TAF). Efficacy was high for all treatments. The most common AEs in ≥50 were nasopharyngitis (20%,22%,25%), diarrhea (19%,22%,8%), and upper respiratory tract infection (16%,17%,12%) and in <50 were diarrhea (19%,18%,18%), headache (17%,18%,19%), and nausea (11%,26%,15%). Treatment-related AEs occurred in 24%,37%, and 29% among ≥50; and 26%,43% and 29% in <50 yrs (p<0.001 for B/F/TAF vs DTG/ABC/3TC). AEs leading to discontinuation in ≥50 occurred in 2% on B/F/TAF, 5% on DTG/ABC/3TC and 7% on DTG+F/TAF compared to 1% in each group for <50 yrs. For ≥50 with AEs leading to discontinuation, 1 on B/F/TAF, 1 on DTG/ABC/3TC and 3 on DTG+F/TAF were treatment-related. In Study 1489, mean % changes in BMD, proteinuria, and renal biomarkers were similar between B/F/TAF to DTG/ABC/3TC. Across groups, there were small changes from baseline in fasting lipids. Median weight increased with no significant difference between groups.

Conclusions:

Through 144W, B/F/TAF was effective and well tolerated in adults ≥ 50 yrs with no clinically significant impact on bone or renal safety, fasting lipids, or weight. B/F/TAF provides a safe and effective treatment option for older adults.

Disclosure

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