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P-547. Efficacy and Safety of B/F/TAF in Treatment-Naïve People With HIV Aged ≥ 50 Years: 5-Year Follow-Up From Two Phase 3 Studies

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Background. An increasing proportion of people with HIV (PWH) are aged ≥ 50 years, with a greater burden of age-related comorbidities; however, long-term analyses of this population are limited. We present key treatment outcomes through 5 years of first-line therapy with bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in PWH ≥ 50 vs < 50 years.

Table. Baseline Demographics and Clinical Characteristics, and W240 Outcomes

	Aged ≥ 50 Years N = 96	Aged < 50 Years N = 538
Baseline demographics and clinical characteristics		
Age, years, median (range)	55 (50-71)	30 (18-49)
Region, n (%) US Ex-US	 56 (58.3) 40 (41.7)	 365 (67.8) 173 (32.2)
Male sex at birth, n (%)	81 (84.4)	484 (90.0)
HIV-1 RNA ≤ 100,000 copies/mL, n (%)	73 (76.0)	442 (82.2)
CD4 cell count < 200 cells/μL, n (%)	19 (19.8)	61 (11.3)
Comorbidities, n (%) Hypertension Hyperlipidemia Diabetes mellitus Cardiovascular disease	 46 (47.9) 39 (40.6) 16 (16.7) 6 (6.3)	 52 (9.7) 48 (8.9) 22 (4.1) 8 (1.5)
Efficacy at W240		
HIV-1 RNA < 50 copies/mL,[a] n (%)	n = 68 67 (98.5)	n = 364 359 (98.6)
Change from baseline in CD4 count, cells/μL, mean (SD)	n = 67 291 (221.3)	n = 348 347 (238.2)
Safety up to W240		
≥ 1 study drug–related TEAE, n (%)	25 (26.0)	153 (28.4)
≥ 1 TEAE leading to study drug discontinuation, n (%)	4 (4.2)	6 (1.1)
TE hypertension events,[b] n (%)	n = 51 10 (19.6)	n = 489 61 (12.5)
TE diabetes events,[c] n (%)	n = 78 4 (5.1)	n = 515 9 (1.7)
Clinical parameters at W240		
Change from baseline in body weight, kg, median (Q1, Q3)	n = 68 4.8 (0.7, 10.2)	n = 363 6.4 (2.4, 12.0)
Change from baseline in eGFR,[d] mL/min, median (Q1, Q3)	n = 67 -10.5 (-19.6, 2.4)	n = 363 -7.7 (-19.4, 3.0)
Change from baseline in fasting TC:HDL ratio, median (Q1, Q3)	n = 65 -0.3 (-0.9, 0.4)	n = 345 0.1 (-0.4, 0.6)
Change from baseline in hip BMD, %, mean (SD)	n = 21 0.3 (3.3)	n = 126 -0.4 (5.8)
Change from baseline in spine BMD, %, mean (SD)	n = 21 1.3 (5.6)	n = 130 -0.9 (4.9)
Adherence up to W240		
Study drug adherence rate during the study,[e] n (%) Low (< 85%) Intermediate (≥ 85% to < 95%) High (≥ 95%)	 n = 93 5 (5.4) 11 (11.8) 77 (82.8)	 n = 531 39 (7.3) 140 (26.4) 352 (66.3)

[a]Missing=excluded; [b]Participants with a medical history of hypertension were excluded; [c]Participants with a medical history of diabetes were excluded; [d]By Cockcroft–Gault equation; [e]Based on pill count for B/F/TAF only; [f]The denominator is the number of participants who returned at least one bottle and had calculable drug adherence
BMD, bone mineral density; B/F/TAF, bictegravir/emtricitabine/tenofovir alafenamide; CD, cluster of differentiation; eGFR, estimated glomerular filtration rate; Ex-US, outside of United States; HDL, high-density lipoprotein; Q, quartile; SD, standard deviation; TC, total cholesterol; TE, treatment-emergent; TEAE, treatment-emergent adverse event; US, United States; W, week

Methods. Studies 1489 (NCT02607930; B/F/TAF vs dolutegravir/abacavir/lamivudine [DTG/ABC/3TC]) and 1490 (NCT02607956; B/F/TAF vs DTG+F/TAF) were randomized, double-blind, multicenter Phase 3 studies in adult PWH. This pooled analysis reports outcomes for participants ≥ 50 vs < 50 years who received B/F/TAF in the 144-week (W) randomization phase and the 96W open-label extension. Baseline demographics and clinical characteristics; proportion of participants with HIV-1 RNA < 50 copies/mL (missing=excluded); adherence; changes in CD4 cell count and metabolic, renal, and bone parameters; and treatment-emergent adverse events (TEAEs) are presented.

Results. Overall, 634 participants received B/F/TAF up to W240; 96 (15.1%) were ≥ 50 years and 538 (84.9%) were < 50 years. Baseline demographics, clinical characteristics, and outcomes are shown in the Table. Higher rates of baseline comorbidities were observed in those aged ≥ 50 vs < 50 years. Both groups had high rates of HIV suppression at W240. A greater proportion of participants aged ≥ 50 vs < 50 years had ≥ 95% adherence (82.8% vs 66.3%; P=0.0015). Changes in CD4 count, weight, eGFR, fasting total cholesterol to high-density lipoprotein ratio, and hip and spine bone mineral density were similar between groups. Proportions of participants with study drug-related TEAEs were similar between groups, with few participants experiencing a TEAE leading to study drug discontinuation. Proportions of TE hypertension and diabetes were modestly higher in the ≥ 50 group vs the < 50 group.

Conclusion. Over 5 years, participants ≥ 50 years were more likely to have high adherence to B/F/TAF treatment vs those < 50 years, with low rates of discontinuations due to AEs in both groups. B/F/TAF maintained high rates of virologic suppression, was well tolerated, and resulted in similar changes in metabolic, renal, and bone parameters in both groups, supporting its use for long-term management of HIV in older PWH.

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