96 Week Efficacy and Safety of B/F/TAF in Treatment-Naive Adults and Adults 250 Years
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Introduction

• Nearly half of people living with HIV in the USA and Europe are aged ≥50 y, and that proportion is expected to grow as people age on antiretroviral therapy¹
• Identifying highly effective and safe antiretroviral regimens in the context of medical comorbidities and drug-drug interactions is of heightened importance in older adults

The single-tablet regimen bictegravir (BIC), etravirine (ETV), and tenofovir alafenamide (TAF) is a guideline-recommended regimen with demonstrated safety and efficacy, and a high barrier to resistance.

B/F/TAF may be a beneficial option for older adults due to its excellent tolerability and few drug interactions.

Objective

To compare the long-term safety and efficacy of B/F/TAF vs DTG/ABC/3TC in adults aged ≥50 y.

Methods

Study Designs: Randomized, Double Blind, Active Controlled

Baseline Characteristics

No resistance to any components of the treatment regimens occurred in any treatment group.

Overall Safety Through Week 96

There were no statistically significant differences in changes in lipids in the overall population.

Changes in BMD Through Week 96 (Study 1489 only)*

Changes From Baseline in Renal Biomarkers at Week 96 (Study 1449 only)*

Changes From Baseline in Fasting Lipids at Week 96 Overall

Conclusions

There were no statistically significant differences in changes in lipids in adults aged ≥50 y.

Similar percentages of participants in each group received lipid-modifying agents at study entry (B/F/TAF 24%, DTG/ABC/3TC 23.3%, and DTG + F/TAF 24.5%) and initiated treatment during the study (3.8%, 3.8%, and 3.7%, respectively).

There were no clinically relevant differences in changes in lipids in the overall population.

Related AEs for adults aged ≥50 y were comparable to those for the overall study population.

The initial treatment for HIV-1 with B/F/TAF was noninferior to either DTG-based regimen at Week 96 by FDA snapshot algorithm, with high rates of virologic suppression in all treatment arms.

Efficacy in adults aged ≥50 y was comparable to that in the overall study population.

There was no treatment-emergent resistance observed in any treatment arm.

There were few AEs leading to discontinuations.

B/F/TAF was associated with fewer treatment-related AEs than DTG/ABC/3TC (p < 0.001) in the overall population.

There were no clinically significant differences in median changes from baseline in total cholesterol, LDL, and total cholesterol/HDL ratio between treatments in the overall population and age ≥25 y subgroup, and no differences in the proportions of participants initiating lipid-lowering therapy.

References

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NCT02607930

Overall Study Participants Adults Aged ≥50 y

Overall Aged ≥50 y

n=320

n=325

n=315

DTG/ABC/3TC placebo qd

DTG/ABC/3TC qd

DTG + F/TAF

B/F/TAF

Week 96

Overall Aged ≥50 y

Changes in BMD Through Week 96 (Study 1489 only)*

Changes From Baseline in Renal Biomarkers at Week 96 (Study 1449 only)*

Changes From Baseline in Fasting Lipids at Week 96 Overall

Conclusions

• Initial treatment for HIV-1 with B/F/TAF was noninferior to either DTG-based regimen at Week 96 by FDA snapshot algorithm, with high rates of virologic suppression in all treatment arms
• Efficacy in adults aged ≥50 y was comparable to that in the overall study population
• There was no treatment-emergent resistance observed in any treatment arm
• There were few AEs leading to discontinuations
• Reported AEs for adults aged ≥50 y were comparable to those for the overall study population
• B/F/TAF was associated with fewer treatment-related AEs than DTG/ABC/3TC (p < 0.001) in the overall population
• Changes from baseline in bone mineral density and renal markers were comparable between treatment arms, with no cases of proximal renal tubulopathy
• Bone and renal safety findings were consistent in adults aged ≥50 y
• There were no clinically significant differences in median changes from baseline in total cholesterol, LDL, and total cholesterol/HDL ratio between treatments in the overall population and age ≥25 y subgroup, and no differences in the proportions of participants initiating lipid-lowering therapy.