Outcomes After Switching From 144 Weeks of Blinded DTG/ABC/3TC or DTG+F/TAF to 96 Weeks of Open-label B/F/TAF

Introduction

- HIV guidelines offer switch strategies for people with HIV-1 (PWH) who are virologically suppressed (eg, history consistent with no integrase [IN] strand transfer inhibitor [INSTI] resistance mutations), but long-term clinical follow-up after the regimen switch is often lacking
- Bictegravir/tenofovir alafenamide (B/F/TAF) is a guideline-recommended regimen for most PWH and is indicated for those with no INSTI treatment history or as a switch regimen in virologically suppressed PWH
- In addition, it is recommended for rapid initiation due to its high barrier to resistance, favorable drug-drug interaction profile, and once-daily dosing without food restrictions

Objective

- To evaluate 96-week outcomes on open-label (OL) B/F/TAF that followed 144 weeks of blinded dolutegravir (DTG)-based treatment in two Phase 3 studies of PWH initiating treatment

Methods

- Study Designs: Randomized, Double Blind, Active Controlled
- Study 1489: DTG/ABC/3TC→B/F/TAF Study 1490: DTG+F/TAF→B/F/TAF
- Participants who switched from DTG/ABC/3TC to B/F/TAF had HIV-1 RNA ≥ 200 copies/mL at time of switch, both of whom were later found to have M184V and resuppressed on OL B/F/TAF

Results

- Characteristics at B/F/TAF Start:
  - Median CD4 count, cells/mm³ (Q1, Q3): 766 (599, 1023) vs 730 (550, 958)
  - Race/ethnicity, n (%): 47% White, 10% Black, 52% Other
  - Average age: 50 years
- Adverse Events During OLE: Weeks 144-240:
  - Nausea and diarrhea were the 2 most commonly reported AEs in the blinded phase of Studies 1489 and 1490
- Nausea and Diarrhea Incidence and Prevalence Through Week 240:
  - Highest rates of nausea and diarrhea were observed with B/F/TAF
- Virologic Outcomes Through Week 240/OLE Week 96:
  - HIV-1 RNA < 50 Copies/mL (M = E)
  - Participants who switched from DTG/ABC/3TC or DTG+F/TAF to OL B/F/TAF maintained high levels of virologic suppression through Week 240/OLE Week 96 (M = E)

Conclusions

- Over 5 years of follow-up in adults initially taking DTG/ABC/3TC or DTG+F/TAF who then switched to B/F/TAF and were followed for 96 weeks, we observed:
  - High rates of virologic suppression with no treatment-emergent resistance to B/F/TAF
  - No participant had HIV-1 RNA ≥ 200 copies/mL, with M184V at the time of switching from DTG/ABC/3TC and both subsequently had sustained resuppression on B/F/TAF
- eGFR Changes During OLE: Weeks 144-240:
  - There were no reported cases of proximal renal tubulopathy and no D/Cs due to renal AEs for participants receiving B/F/TAF
- Nausea and Diarrhea Incidence and Prevalence Through Week 240:
  - No cases of glycosuria occurred in participants without diabetes or concomitant hyperglycemia

- Laboratory Abnormalities During OLE: Weeks 144-240:
  - No cases of hyperglycemia were observed in participants who switched from DTG/ABC/3TC to B/F/TAF

- Continued B/F/TAF

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