

## SWITCH TO BICTEGRAVIR/F/TAF FROM DTG AND ABC/3TC

### Authors:

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### Background:

We report the primary Week (W) 48 efficacy and safety Phase 3 results of switching to bicitgravir/emtricitabine/tenofovir alafenamide (B/F/TAF) from dolutegravir plus abacavir/lamivudine (DTG+ABC/3TC) or DTG/ABC/3TC.

### Methods:

HIV-infected adults virologically suppressed on DTG/ABC/3TC or DTG plus ABC/3TC (DTG/ABC/3TC group), with estimated glomerular filtration rate (eGFR)  $\geq 50$  mL/min were randomised 1:1 to switch to B/F/TAF (50/200/25 mg) once daily or continue current regimen as DTG/ABC/3TC through week 48 in a double-blinded fashion. Primary endpoint was proportion with HIV-1 RNA  $\geq 50$  copies/mL at W48 (FDA snapshot). Noninferiority was assessed through 95.002% confidence intervals (CI) using a margin of 4%.

### Results:

563 participants were randomised and treated (B/F/TAF n=282, DTG/ABC/3TC n=281): 11% women, 22% Black, median age 46 yrs (range 20-71). At W48, 1.1% switching to B/F/TAF and 0.4% continuing DTG/ABC/3TC had HIV-1 RNA  $\geq 50$  copies/mL (difference 0.7%; 95%CI -1.0% to 2.8%, p=0.62), demonstrating noninferiority. At W48, proportion with HIV-1 RNA  $< 50$  copies/mL was 93.6% on B/F/TAF and 95.0% on DTG/ABC/3TC. No participant developed resistance to any study drug. The most common adverse events (AEs) were upper respiratory tract infection (10% B/F/TAF, 10% DTG/ABC/3TC), diarrhea (9%, 5%), nasopharyngitis (7%, 8%) and headache (7%, 7%). Few participants (6 [2%], 2 [1%]) had AEs leading to premature study drug discontinuation. Mean bone mineral density increased similarly in both groups. Percentage changes from baseline in renal biomarkers were similar between treatment groups. Lipid parameters were similar between groups with the exception of a small decrease in triglycerides (-5 mg/dL) seen in the B/F/TAF group vs. +3 mg/dL in the DTG/ABC/3TC group (p=0.028).

### Conclusion:

Switching to B/F/TAF was noninferior to continuing DTG/ABC/3TC with low rates of W48 virologic failure, high rates of maintained virologic suppression, and no resistance. B/F/TAF was well tolerated, with a similar bone and urine protein safety profile to DTG/ABC/3TC.

**Disclosure of Interest Statement:**

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