A PHASE 3B OPEN-LABEL PILOT STUDY TO EVALUATE SWITCHING TO ELVITEGRAVIR/COBICISTAT/ EMTRICITABINE/TENOFOVIR ALAFENAMIDE (E/C/F/TAF) SINGLE TABLET REGIMEN IN VIROLOGICALLY-SUPPRESSED HIV-1 INFECTED ADULTS HARBORING THE NRTI RESISTANCE MUTATION M184V AND/OR M184I (GS-US-292-1824)

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Background:
This study evaluated the efficacy and safety of E/C/F/TAF in subjects whose HIV-1 harbors the M184V/I mutation.

Methods:
1824 is an ongoing, prospective, open-label, single arm, multicenter study in subjects receiving a stable regimen(≥6 months) of emtricitabine/tenofovir disoproxil fumarate or abacavir/lamivudine plus a third antiretroviral agent. Subjects had HIV-1 RNA <50 copies/ mL and a historical genotype report showing M184V and/or M184I and no evidence of previous virologic failure or resistance to boosted protease inhibitors(PIs) or integrase strand transfer inhibitors(INSTIs). The primary objective was efficacy of switching to E/C/F/TAF in maintaining HIV-1 RNA<50 copies/mL at Week 12 using pure virologic response (PVR). Subjects with discontinuation or missing values were considered responders if last HIV-1 RNA<50 copies/mL.

Results:
Thirty-seven subjects enrolled and switched to E/C/F/TAF; mean age 50yrs (range 22-76), 73% White, 22% women and median CD4 count 724 cells/μL. Prior regimens were 2 nucleoside reverse transcriptase inhibitors(NRTIs) plus boosted PI(54%), INSTI(32%), non-NRTI(NNRTI) (11%), and INSTI+NNRTI (3%). 51% (19/37) had NNRTI resistance mutations on historic resistance tests. All 37 subjects(100%) maintained HIV-1 RNA<50 copies/mL by Week 12. Three subjects discontinued prior to Week 12 with the last recorded HIV-1 RNA<50 copies/mL. There were no virologic failures or cases of emergent resistance. There was no significant change in CD4 count to Week 12. Four serious adverse events (AEs) occurred that were not considered study drug-related: 1 each of squamous cell carcinoma, acute kidney injury (due to poorly controlled hypertension and diabetes), transient proteinuria which resolved while on study drug and pulmonary embolism. 19%(7/37) of subjects experienced any study drug-related AE; none were grade 3 or 4. One subject experienced an AE(muscle spasms) leading to premature E/C/F/TAF discontinuation.

Conclusion:
In this primary analysis, 100% of HIV-1 suppressed subjects with baseline M184V/I mutations who switched to E/C/F/TAF maintained HIV suppression at Week 12.

Disclosure of Interest Statement:
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