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1381. No Emergent Resistance in HIV-1 Infected Virologically-Suppressed Subjects Who Switched to R/F/TAF

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Background. GS-US-366-1216 and GS-US-366-1160 are randomized, double-blind, phase 3b studies evaluating the safety and efficacy of switching to rilpivirine/emtricitabine/tenofovir alafenamide (R/F/TAF) from R/F/tenofovir disoproxil fumarate (TDF) or efavirenz (EFV)/F/TDF, respectively, in HIV-1-infected virologically-suppressed subjects. At Week 48, switching to R/F/TAF was non-inferior to staying on R/F/TDF (94% vs. 94%, respectively) or EFV/F/TDF (90% vs. 92%) for HIV-1 RNA <50 c/mL (virologic success) by FDA snapshot analysis. Here, we present integrated resistance analyses of these two studies through Week 48.

Methods. Historical genotypes were collected when available. Subjects in the resistance analysis population (subjects with HIV-1 RNA ≥400 c/mL at virologic failure, discontinuation, or Week 48) had genotypic/phenotypic analyses at failure for protease and reverse transcriptase (RT; PhenoSense GT, Monogram). Subjects with post-baseline resistance mutations detected had their baseline proviral DNA analyzed retrospectively (GenoSure Archive, Monogram).

Results. Of the 1504 randomized and treated subjects, resistance development was analyzed for 7 subjects (0.9%; 7/754) on R/F/TAF, 1 subject (0.3%; 1/313) on R/F/TDF, and 2 subjects (0.5%; 2/437) on EFV/F/TDF. No R/F/TAF (0%) or R/F/TDF (0%) subjects developed primary NNRTI or NRTI resistance mutations. One EFV/F/TDF subject (0.2%; 1/437) developed primary NNRTI and NRTI resistance mutations (NNRTI: Y188L; NRTI: M184V). Three subjects on R/F/TAF had virologic rebound with mutations also detected at baseline by proviral DNA analysis. Historical genotypes were available for 527 subjects; virologic success rates were high among subjects with pre-existing mutations (Table 1).

Table 1. Virologic success rates of subjects with mutations by historical genotype.

	Subjects with success/subjects with mutation (%)		
RT mutation	R/F/TAF	R/F/TDF	EFV/F/TDF
K101E	1/1 (100%)	0	0
K103N	10/11[a] (91%)	6/7[a] (86%)	1/1 (100%)
E138A/K	2/3[a] (67%)	2/2 (100%)	0
M184V	1/2[a] (50%)	1/1 (100%)	0

[a]1 subject discontinued prior to Week 48 with HIV-1 RNA <50 c/mL.

Conclusion. No emergent resistance to any of the components of R/F/TAF was detected through 48 weeks after switching. Virologic success rates were high among subjects with pre-existing mutations.

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1382. Sword 1 and 2: Subgroup Analysis of 48 Week Results by Age, Race and Gender

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Background. Switching to the 2-drug regimen (2DR) of DTG+RPV was proven non-inferior to continuing a suppressive PI-, INI- or NNRTI- based current antiretroviral regimen (CAR) at Week 48. This analysis evaluated the efficacy and safety of switching from CAR to DTG+RPV by age, race and gender subgroups.

Methods. Two identically designed, open-label, multicenter, global, phase III, non-inferiority studies compared the efficacy and safety of switching from a 3 or 4-drug CAR to DTG + RPV once daily in HIV-1-infected adults, with HIV-1 RNA<50 c/mL. Primary endpoint was proportion of patients with VL<50 c/mL at Wk48 using FDA Snapshot. Additional analysis were performed to summarize efficacy base on age, race and gender subgroups for each individual study and pooled.

Results. 1024 patients were randomized and exposed (DTG+RPV 513; CAR 511), across both studies. Treatment arms were well matched for demographic and baseline characteristics. Median age across both arms was 43.4 years, with 29% and 28% ≥ 50 years in DTG+RPV and CAR, respectively. 23% and 21% were female while 18% and 22% were non-white for DTG+RPV and CAR. For the pooled studies and for SWORD-1 and SWORD-2 individually, switching to DTG+RPV was non-inferior to CAR at Wk48. Similar response rates were observed in the DTG+RPV arm compared with CAR across subgroups (Table 1). More AEs were reported in the DTG+/RPV arm across all subgroups except Asian race; no unexpected AEs were identified for either drug.

Table 1. Proportion of patients with HIV-1 RNA <50 c/mL at Week 48 (snapshot): pooled SWORD studies population

	DTG/RPV, *N* = 513, *n*/*N* (%)	CAR, *N* = 511, *n*/*N* (%)
Overall	486/513 (95)	486/511 (95)
Age		
<50 years	350/366 (96)	348/369 (94)
≥50 years	136/147 (93)	137/142 (96)
Gender		
Male	375/393 (95)	387/403 (96)
Female	111/120 (93)	98/108 (91)
Race		
White	395/421 (94)	378/398 (95)
African heritage	36/37 (97)	44/47 (94)
Other	17/17 (100)	14/16 (88)
Asian	38/38 (100)	49/50 (98)

Conclusion. Switch to a novel, once daily 2DR of DTG+RPV in patients with a suppressed viral load, was an effective and well tolerated treatment option across age, race, and gender subgroups which were consistent with overall results.

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1383. Efficacy and Safety of Tenofovir Alafenamide vs. Tenofovir Disoproxil Fumarate in HIV-infected, Virologically Suppressed Black and Non-Blacks Adults Through Week 96: Subgroup Analysis of a Randomized Switch Study

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