ICAAC 2014 – STRATEGY Study: 115 and 121 Analysis by Blacks and Nonblacks

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Topics: H2. Antiretroviral Agents for Treatment and Prevention Including Preclinical and All Phases of Clinical Trials, PK/PD and resistance

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Switch to E/C/F/TDF from PI+RTV or NNRTI plus FTC/TDF Maintains HIV Suppression at Week 48 and is Safe in Black Subjects

Background: The STRATEGY(S)-PI and STRATEGY(S)-NNRTI open label trials demonstrated that switch to elvitegravir/cobicistat/emtricitabine/tenofovir DF (E/C/F/TDF) from ritonavir-boosted protease inhibitor (PI+RTV) or non-nucleoside reverse transcriptase inhibitor (NNRTI) plus emtricitabine/tenofovir DF (FTC/TDF) was virologically noninferior (S-PI: 94% E/C/F/TDF vs 87% PI; S-NNRTI: 93% E/C/F/TDF vs 88% NNRTI) and safe at Week 48. We report the safety and efficacy of E/C/F/TDF in Black subjects from these studies.

Methods: Retrospective subgroup post-hoc analysis of efficacy by FDA snapshot analysis and safety of E/C/F/TDF vs PI or NNRTI + FTC/TDF in Black subjects through Week 48.

Results: In S-PI: 433 subjects were randomized with 63 (15%) Black subjects (43 E/C/F/TDF, 20 PI; 68% males). In S-NNRTI: 434 subjects were randomized with 72 (17%) Black subjects (49 E/C/F/TDF, 23 PI; 74% males). At Week 48, 95% E/C/F/TDF vs 89% PI and 92% E/C/F/TDF vs 74% NNRTI maintained HIV-1 RNA < 50 copies/mL by FDA snapshot analysis. There was no virologic failure in the E/C/F/TDF and PI groups and one in the NNRTI group with no emergent resistance. Adverse events leading to discontinuation were infrequent; there were no cases of proximal renal tubulopathy in any group. An expected decrease (median) from baseline in eGFR (mL/min) for E/C/F/TDF was observed at week 4 and remained non-progressive through week 48 (S-PI: -11.1 E/C/F/TDF vs -1.4 PI; S-NNRTI: -12.2 E/C/F/TDF vs -3.0 NNRTI), consistent with cobicistat inhibition of renal creatinine transporters.
**Conclusion:** Black subjects who switched to E/C/F/TDF had numerically higher rates of virologic success at Week 48. There was no development of resistance and E/C/F/TDF was safe. E/C/F/TDF may be a treatment option for Black virologically suppressed subjects who switch from their current regimens.