Characterization of Virologic Failure Over 96 Weeks by Drug Resistance and Antiviral Response in ART Naïve Patients Receiving Abacavir/Lamivudine (ABC/3TC) or Tenofovir/Emtricitabine (TDF/FTC) Each with Lopinavir/Ritonavir QD in the HEAT Study

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Background
- The HEAT study is the first head-to-head study to evaluate the efficacy and safety of the dual NRTI backbones Epzicom and Truvada each in combination with Kaletra QD over 96 weeks in naive subjects.

Objectives
- To characterize resistance patterns that arise in subjects experiencing virologic failure in the baseline HIV-1 RNA strata of <100,000 and never suppressing to <200 c/mL by Week 24 as compared to ABC/3TC
- Protocol-Defined Virologic Failure
- Subjects with confirmed HIV-1 RNA >100,000 c/mL at one assessment, or confirmed reduction to <50 c/mL by week 24.

Results

Figure 1. Efficacy Results through Week 96

Table 1. Virologic Failure Through Week 96 (ITT—E)

Table 2. Summary of Treatment Emergent Resistance in Subjects with Protocol-defined Virologic Failure

Table 3. Phenotypic Correlations to Treatment-emergent Mutations or Mixtures at Codon 154

Figure 2. Virologic Failure by Baseline HIV-1 RNA strata

Figure 3. Virologic Failure by Baseline HIV-1 RNA Strata and Failure Criterion

Figure 4. Subject Profile

Discussion
- Overall virologic failure rates were similar across both treatment arms. Among subjects with baseline HIV-1 RNA <100,000 c/mL, more ABC/3TC subjects experienced virologic failure (ABC/3TC: 14% vs TDF/FTC: 0%). Among subjects with baseline HIV-1 RNA >100,000 c/mL, more ABC/3TC subjects experienced virologic failure (ABC/3TC: 14% vs TDF/FTC: 0%).

Conclusions
- The number of subjects with protocol-defined virologic failure was similar between the two treatment groups (ABC/3TC: 14% vs TDF/FTC: 14%). The TDF/FTC treatment group had 63% of subjects experiencing virologic failure in the baseline HIV-1 RNA strata of >100,000 c/mL, while in the ABC/3TC group 58% of subjects experienced virologic failure in the baseline HIV-1 RNA strata of >100,000 c/mL.

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