SYNOPSIS

Clinical Study Report for Study AI424494

TITLE OF STUDY: A 48-Week, Randomized, Open-Label Phase 3b Study Comparing the Antiviral Efficacy and Safety of ATV/RTV Plus 3TC with ATV/RTV plus TDF/FTC in HIV-1-Infected, Treatment-Naïve Subjects, Followed by a 48-Week Period on ATV/RTV Plus 3TC

PURPOSE: The experimental regimen (Atazanavir, heat-stable ritonavir [ATV/RTV_{HS}] 300/100mg QD + lamivudine [3TC] 300mg once daily [QD]) was hypothesized to have similar (non-inferior) efficacy compared with a standard daily regimen consisting of ATV/RTV_{HS} 300/100 mg QD + tenofovir/emtricitabine [TDF/FTC] 300/200mg QD in antiretroviral-naïve subjects, as assessed by the proportion of subjects with human immunodeficiency virus (HIV) ribonucleic acid (RNA) < 40 c/mL at Week 48.

This was an open-label, prospective, randomized, multicenter, 96-week study with a planned primary efficacy endpoint at 48 weeks, followed by an open-label, single arm, 48 week phase. The study was designed to compare the efficacy of ATV/RTV_{HS} plus 3TC vs. ATV/RTV_{HS} plus TDF/FTC in treatment-naïve HIV-1-infected subjects.

NUMBER OF SUBJECTS: 8 screened, 3 randomized/treated

DISPOSITION, DEMOGRAPHICS AND OTHER PERTINENT BASELINE CHARACTERISTICS:

Three subjects with an HIV-1 diagnosis who met eligibility criteria were randomized. All 3 subjects were discontinued from the study due to early study termination.

SUMMARY OF SAFETY RESULTS:

Eight subjects were screened for the study, and three of the eight subjects were randomized. Five subjects were discontinued from the study prior to randomization due to early termination of the study by the sponsor. The three randomized subjects were also discontinued from the study due to early termination of the study. There were no adverse events reported.

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