Gilead 236-0128-WAVES
(Clinician Summary Sheet)
A Randomized, Double-blind Phase 3B Study to Evaluate the Safety and Efficacy of Elvitegravir/Cobicistat/Emtricitabine/Tenofovir Disoproxil Fumarate Versus Ritonavir-Boosted Atazanavir Plus Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1-Infected, Antiretroviral Treatment-Naïve Women

Brief Summary:
The purpose of this study is to determine if Stribld (EVG/COBI/FTC/TDF) is safe and effective in reducing levels of HIV-1 in female subjects who are treatment-naïve women.

Primary Objective:
To evaluate the efficacy of a regimen containing EVG/COBI/FTC/TDF versus RTV-boosted ATV plus FTC/TDF in HIV-1 infected, ARV treatment-naïve women to as determined by the achievement of HIV-1 RNA <50 copies/mL at Week 48

Inclusion Criteria:
1. Female (at birth) age 18 years and older
2. Plasma HIV-1 RNA levels >500 copies/ML
3. No prior use if any approved or investigational ARVs for any length of time.
4. Screening genotype report provided by Gilead must show sensitivity to FTC, TDF, and ATV/r.
5. Normal ECG (or if abnormal, determined by the Investigator to be not clinically significant)
6. Women of childbearing potential must agree to utilize the protocol-recommended contraceptive methods of:
   ➢ A combination of one hormonal method and one barrier method;
   ➢ Two barrier methods where one method is a male condom; or
   ➢ Use of an IUD or tubal sterilization

Exclusion Criteria:
1. A new AIDS-defining condition diagnosed within 30 days prior to screening.
2. Subjects receiving drug treatment for Hepatitis C, or subjects who are anticipated to receive treatment for Hepatitis C during the course of the study.
3. Subjects experiencing decompensated cirrhosis.
4. Females who are breastfeeding
5. Positive serum pregnancy test
6. Have an implanted defibrillator or pacemaker
7. Have an ECG PR interval >220msec
8. A history of malignancy within the past 5 years (prior to screening) or ongoing malignancy other than KS, basal cell carcinoma, or resected, non-invasive cutaneous squamous carcinoma.
   ➢ Note: Subjects with cutaneous KS are eligible, but must not have received any systemic therapy for KS within 30 days of baseline and must not be anticipated to require systemic therapy during the study.
9. Active, serious infections requiring parenteral antibiotic or antifungal therapy within 30 days prior to baseline.

Treatment:
Arm A: Stribld + Placebo to match ATV/r plus FTC/TDF
Arm B: ATV/r plus FTC/TDF + Placebo to match Stribld

Duration of Study:
Participants will be on study for 48 weeks.

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