A fixed dose combination of elvitegravir, cobicitabine, emtricitabine, tenofovir disoproxil fumarate for the initial treatment of HIV-2 infection: 24 week results of a pilot study in Senegal, West Africa.

(24-Week Results of Elvitegravir-Cobicistat-Emtricitabine-Tenofovir DF for HIV-2)

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Abstract: 961

BACKGROUND:

There is an urgent need for safe and effective antiretroviral therapy (ART) for HIV-2 infection. HIV-2 treatment is complicated by intrinsic resistance to many FDA-approved HIV-1 drugs, and multidrug-resistance is common in individuals failing ART. There are limited options for 1st- and 2nd-line ART for HIV-2 in resource-limited settings. An increasing body of data suggests that integrase-based therapies may have potential utility for the treatment of HIV-2. We have undertaken the first clinical trial of a once-daily fixed-dose combination pill containing elvitegravir, cobicitabine, emtricitabine, tenofovir disoproxil fumarate (EVG/c-FTC-TDF; Stribild [Gilead Sciences, Inc.]) to assess the effectiveness of this regimen in HIV-2-infected subjects in Senegal, West Africa.

AIMS:

To Assess the Safety and Efficacy of once-daily single tablet regimen of elvitegravir, cobicitabine, emtricitabine, tenofovir disoproxil fumarate (EVG/c-FTC-TDF; Stribild) in ARV-naive HIV-2 infected adults in Senegal, West Africa. Results presented are a 24 week interim analysis.

METHODS:

The study (Clinical Trials #: NCT02180438) was conducted at the Service des Maladies Infectieuses Ibrahima DIOP Mar, Centre Hospitalier Universitaire de Fann, Universite Cheikh Anta Diop de Dakar, Dakar, Senegal. HIV-2-infected, ART-naive adults with WHO stage 3 or 4 disease or CD4 counts below 750 cells/mm³ were eligible for this open-label pilot trial, with planned enrollment of 30 subjects and follow-up for 48 weeks. Enrolled subjects are monitored every four weeks for clinical and immuno-virologic outcomes as well as adverse events. For this 24-week interim analysis, changes in HIV-2 plasma viral load, CD4 counts, adverse events, all-cause mortality and loss to follow-up were analyzed. Undetectable HIV-2 plasma RNA viral load was defined as <10 copies/ml (Chang et al. JCV 2012).

RESULTS:

TABLE 1. Baseline Characteristics of ARV-naïve HIV-2 infected subjects initiating elvitegravir, cobicitabine, emtricitabine, tenofovir disoproxil fumarate and completing 24 weeks follow up (n=14)

<table>
<thead>
<tr>
<th>Baseline WHO stage</th>
<th>Screened</th>
<th>Enrolled</th>
<th>Completed 24 weeks</th>
<th>Withdrawn</th>
<th>Dead</th>
<th>Lost to follow up</th>
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Baseline BMI, median (IQR) 25.1 (20.6-30.5)
Baseline CD4 count, cells/mm³, median (IQR) 386 (330-467)

Baseline HIV-2 plasma viral load:
- Not detected, n (%) 3 (21.4)
- Detected, <10 copies/ml (quantifiable limit), n (%)* 2 (14.3)
- Detected, copies per mL, median (range)# 28 (10-62)

* Among those with quantifiable viral loads; Data as of 2/11/16

CD4 Count Trajectories

BMI  Trajectories

HIV-2 Virologic Suppression

CONCLUSIONS:

Long-term outcomes of HIV-2 infected patients on ART in West Africa are suboptimal and new therapeutic options are needed. Initial data suggest that EVG/c-FTC-TDF, a once-daily single-tablet regimen, is safe, effective, and well-tolerated in this population. Our findings support the use of integrase inhibitor-based regimens for HIV-2 treatment.