Switching Undetectables to Once Daily Selzentry: The SUDS Study

Stanley T. Lewis, MD, MPH1, Kenneth P. Degazon, MD1, Chymbeelyn B. Larisma, MD1, Katherine Asuncion, MD1
St. Hope Foundation, Inc., Houston, TX
ID Week October 26-30, New Orleans, LA

Introduction

- Treatment of Human Immunodeficiency Virus (HIV-1) requires a combination of antiretroviral medications.
- Most patients prefer once daily (OD) regimens.
- Maraviroc (MVC), a chemokine co-receptor 5 (CCR5) antagonist, is approved for treatment of HIV at 150mg BID or 300mg BID.
- Trofile® DNA enables assessment of viral tropism in virologically suppressed patients.
- SUDS: pilot study to evaluate switching virologically suppressed patients to once daily (OD) MVC-based regimens.

Objectives

The objective of the study was to determine if regimen tolerability/toxicity could be maintained or improved while maintaining virologic suppression following a switch to once daily Maraviroc.

Methods

- St. Hope Foundation’s database was queried to identify HIV positive patients on non-MVC containing regimens with CCR5 tropism.
- A Trofile® DNA was used to document CCR5 tropism. Patients with history of dual/mixed or CXCR4-tropic HIV-1 were excluded from participation.
- Patients must have had an HIV-1 RNA <100 copies/mL for ≥3 months on their first HIV treatment regimen.
- 32 patients were enrolled (mean age 42 years, 75% males). The majority of patients were Black (59%) with 22% Hispanic, 16% White, and 3% Asian.
- Patients with prior exposure to Maraviroc were also excluded.
- Patients that qualified for participation, discontinued the PI, NNRTI, or Integrase inhibitor portion of their regimen and began Maraviroc 600mg QD. Patients continued their two (2) NRTIs.
- Patients were monitored every four to eight weeks for safety and efficacy.
- Maraviroc Dosages: 600 mg (2 tablets of 300 mg taken with food once daily for 48 weeks).

Key Inclusion/Exclusion Criteria

Key Inclusion criteria
- Viral load <100 copies/mL and documented CCR5 tropic virus
- Taking first combination antiretroviral regimen (cART) composed of one NNRTI, or one PI (including boosted PIs), or one integrase inhibitor; AND two (2) NRTIs

Key Exclusion criteria
- History of virologic failure, resistance associated mutations, dual/mixed- or CXCR4-tropic virus
- HCV infection requiring treatment during the study period
- Any clinically significant allergy or hypersensitivity to maraviroc
- Any grade 3 or 4 toxicity according to the Division of AIDS grading scale at screening, except for asymptomatic triglyceride or cholesterol elevation

Study Design

- Single arm, single site, open-labeled switch study
- N = 30 HIV positive patients infected with CCR5 tropic virus
- VL ≤ 100 copies/mL for ≥12 wks on non-MVC containing regimen
- Switch to once daily MVC (600mg qd) plus the same 2 NRTIs.

Results and Disposition

Week 48 interim analysis on 28 patients showed high regimen tolerability, virologic and immunologic efficacy with minimal or no side effects and no serious adverse events. Treatment satisfaction questionnaires showed an overall increased satisfaction with a once daily Maraviroc regimen.

CD4 Count Result

At Week 24, the change in the mean CD4+ T-cell Count from the Baseline measurement was an increase of 92 cells/mm³. At Week 48, the change in mean CD4+ cell count was an increase of 93 cells/mm³.

Safety and Tolerability

Parameters Adverse Events
Systemic Fatigue
Infection Fungal Infection
Dermatological Dermatitis
Cardiovascular Hypertension
Gastrointestinal Nausea
Neurological Depression
Respiratory URI
Musculoskeletal Muscle Spasm/Pain
Genitourinary Urethritis
Metabolic Weight Gain
Total

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Conclusions

Switching virologically suppressed patients from PI, NNRTI, and II-based regimens to 600mg QD Maraviroc proved to be safe and effective. This study demonstrated positive impact on patients and adherence to treatment regimen.

Lipid Panel Mean Change from Baseline

- Cholesterol, mean change from baseline (mg/dl): T. Cholesterol -2.3; LDL 0 HDL 5.4; TG – 41.11