High Levels of Patient Satisfaction During Rapidly Initiated Therapy With Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) for Treatment of HIV-1 Infection Through 24 Weeks of the DIAMOND Study

Carmela Benson,1 Richard Bruce Simonson,1 Ceyhun Bicer,1 Keith Dunn1
1Janssen Scientific Affairs, LLC, Titusville, NJ, USA; BICER Consulting & Research, Antwerp, Belgium

INTRODUCTION

- Decreases in viral load are sustained longer in treatment-naive HIV-1 patients on D/C/F/TAF (D/C/TAF) versus other treatments/strategies.
- Rapid initiation of therapy for individuals newly diagnosed with HIV-1 virus has been demonstrated to be effective in reducing morbidity and mortality.
- Guidelines from the World Health Organization support the rapid initiation of ART for newly diagnosed HIV-1 patients in most countries.
- The low proportions of HIV-1–infected individuals in the US who were in receipt of care (63%) or were in treatment (31%) was a major concern for the development of an accessible STR.

OBJECTIVES

- To assess the efficacy and safety of D/C/F/TAF in a rapid initiation model of care.

METHODS

- Study Design:
  - A multicenter, 24-week, Phase 3b trial (NCT02994144) in a compassionate, open-label setting with single-arm, open-label, parallel-group, nonrandomized, multinational, multicenter, 2-arm (D/C/F/TAF vs. D/C/TAF), noninferiority study in patients with HIV-1 infection who were either naive or after a virologic treatment interruption (V1 ≥50 copies/mL).
  - Patients were enrolled at the time of HIV diagnosis. No laboratory or clinical eligibility criteria were used.
  - Eligibility criteria included adults 18 years of age or older with an HIV-1 RNA ≥50 copies/mL within 24 hours of diagnosis.

- Analyses:
  - Primary endpoint: the proportion of patients achieving virologic suppression (HIV-1 RNA <50 copies/mL) with ≥50 weeks of follow-up.
  - Secondary endpoints included all-cause discontinuations and all-grade and grade 3-4 adverse events (AEs).

RESULTS

- Patient Population and Disposition
  - A total of 109 patients were enrolled in the study; 29% were enrolled within 48 hours of diagnosis and the median (range) time from HIV-1 diagnosis to screening/baseline was 5 (0-14) days.
  - Of the 109 patients enrolled, 98 (90%) continued to receive treatment through Week 24, and only 1 patient discontinued the study due to AEs.

- Efficacy:
  - At Week 24, 99% of patients had undetectable HIV-1 RNA ≤50 copies/mL.
  - Among patients with ≥50 weeks of follow-up, 89% had undetectable HIV-1 RNA ≤50 copies/mL.

- Safety:
  - There were no new safety concerns identified with D/C/F/TAF in this trial.

- Conclusions:
  - D/C/F/TAF demonstrated high levels of patient satisfaction and high viral suppression through 24 weeks of treatment.

REFERENCES

- CD4 cell count
- HIV-1 RNA
- WHO stage
- ART
- PI
- Integrase
- NRTI
- NNRTI
- Treatment
- CD8 count
- TNF-α
- IL-6
- IFN-γ
- IL-17
- IL-23
- IL-12
- IL-10

ACKNOWLEDGMENTS

- This study was conducted in accordance with the Declaration of Helsinki.
- The authors are sole owners of all rights, title, and interest in all data and materials that resulted from the study.
- This study was supported by Janssen Scientific Affairs, LLC.

DISCLOSURES

- The authors have no conflicts of interest to declare.

POSTER PRESENTED AT HIV DRUG THERAPY: GLASGOW 2018; 28-30 OCTOBER, 2018; GLASGOW, UNITED KINGDOM.