Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide (D/C/F/TAF) in a Test-and-Treat Model of Care for HIV-1 Infection: Interim Analysis of the DIAMOND Study

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INTRODUCTION

The DIAMOND study was an open-label, prospective, multicenter, randomized, controlled trial designed to evaluate the efficacy and safety of D/C/F/TAF in a rapid initiation model of care for HIV-1–infected, treatment-naïve patients. The primary objective was to determine the proportion of patients achieving HIV-1 RNA <50 copies/mL at Week 24 on D/C/F/TAF treatment. The secondary objectives included a comparison of tolerability and safety outcomes between D/C/F/TAF and control treatment, and the assessment of virologic failure rates. The study was conducted in the United States, and the data presented here are from the US cohort only.

RESULTS

Patient Population and Disposition

A total of 109 patients were enrolled in the study, of whom 54 were randomized to D/C/F/TAF and 55 to the control treatment. The median age of the patients was 38 years, and the median CD4+ cell count was 413 cells/mm3 at screening/baseline. Most patients were male (82%), and the majority were African American (64%).

Virologic Outcomes

At Week 24, 88 of 109 (81%) patients had achieved HIV-1 RNA <50 copies/mL on D/C/F/TAF treatment. The proportion of patients virologically suppressed was 93.7%, and virologic failure (VF) rates were 0.8% and 0.5% with D/C/F/TAF and control, respectively.

Safety

Safety was assessed by discontinuations due to protocol-defined safety stopping rules, laboratory abnormalities, and adverse events (AEs). The most common AEs were grade 1 or 2 in intensity, and incidences of grade 3 AEs and serious AEs were low. No patients discontinued the study due to lack of efficacy, and no patients had PDVF.

OBJECTIVES

This study was designed to evaluate the efficacy and safety of D/C/F/TAF in a rapid initiation model of care for HIV-1–infected, treatment-naïve patients. The primary objective was to determine the proportion of patients achieving HIV-1 RNA <50 copies/mL at Week 24 on D/C/F/TAF treatment. Secondary objectives included a comparison of tolerability and safety outcomes between D/C/F/TAF and control treatment, and the assessment of virologic failure rates.

METHODS

Study Design

This was a prospective, multicenter, randomized, controlled trial. Patients were randomized to receive D/C/F/TAF (n = 54) or control treatment (n = 55). The study was conducted in the United States, and the data presented here are from the US cohort only.

Statistical Analyses

Fisher’s exact test was used to compare proportions, and the Cochran-Mantel-Haenszel test was used to compare the incidences of AEs between treatment groups.

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REFERENCES


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