HIV Treatment-experienced Patients Switched to D/C/F/TAF: Age, Gender, and Race Analyses

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INTRODUCTION

Objective

The oral, once-daily, single-tablet regimen darunavir/cobicistat/emtricitabine/tenofovir alafenamide (D/C/F/TAF) has been evaluated in pivotal phase 3 trials of both treatment-naive and treatment-experienced HIV-infected patients. In a phase 3 extension of the EMERALD trial, patients on D/C/F/TAF were compared to patients on continuing use of a boosted protease inhibitor (bPI) + emtricitabine (FTC)/tenofovir disoproxil fumarate (TDF), with virologic response and safety as primary endpoints. D/C/F/TAF demonstrated noninferiority to the control therapy through 48 weeks.

Methods

Study design

This open-label, randomized, non-inferiority extension of the EMERALD trial included patients from a total of 378 clinic sites in 37 countries. Eligibility criteria for the trial included virologic suppression (HIV-1 RNA <50 copies/mL) for a minimum of 12 to 24 months prior to screening, and treatment failure with a current regimen containing at least 2 drugs with documented resistance. Patients were randomized 1:1 to either D/C/F/TAF (800/150/200/10 mg) or FTC/TDF (150/200 mg) at the site of consent. Safety and efficacy were evaluated through 48 weeks.

RESULTS

Patient population

At baseline, 763 patients were randomized to D/C/F/TAF and 378 patients were randomized to FTC/TDF. The treatment-naive population included 38% of patients (n = 293). Across subgroups, there were no significant differences in age, sex, race, or demographic characteristics. The overall mean age was 46 years, and 59% of patients were male.

Efficacy

Virologic rebound rates were similar in the D/C/F/TAF and control arms in the overall population and across subgroups at Week 48 (2.4% vs 3.2%, respectively; p = 0.25).

Safety

Low rates of virologic rebound, as well as improved renal function and bone safety, were observed regardless of age, sex, race, or treatment-naive status. Low rates of virologic rebound (2.4%) were observed in the overall population and across subgroups at Week 48.

CONCLUSIONS

The oral, once-daily, single-tablet regimen D/C/F/TAF is well tolerated and generally safe in treatment-experienced patients with HIV in the post-treatment setting. Low rates of virologic rebound, as well as improved renal function and bone safety, were observed regardless of age, sex, race, or treatment-naive status. Low rates of virologic rebound (2.4%) were observed in the overall population and across subgroups at Week 48.

REFERENCES

1. SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) [summary of product characteristics]. Beerse, Belgium: Janssen-Cilag NV; October 2017.

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