Efficacy and Safety of Fosamprenavir + Ritonavir (FPV/RTV) 700mg/100mg Twice Daily (QD) Versus FPV/RTV 1400mg/100mg Once Daily (QD) with ABC/3TC QD over 24 Weeks

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Abstract

IGA1 Treatment trial design was a Phase 2b dose-finding study (60mg FPV/RTV 1400mg QD) followed by a Phase 3 randomized study (1400mg/100mg QD vs 1000mg/100mg BID) with ABC/3TC QD over 24 Weeks. Baseline demographics were similar between arms: median age 38 years; 74% male; 73% Caucasian; CD4+ count 247 cells/mm3. Responses (<400 c/mL) were similar across treatment arms for both low and high viral loads. All patients completing the study had virological suppression. Full analysis showed high antiviral efficacy, good safety and tolerability in both treatment arms and in patients with both low and high viral loads. All subjects will be followed to 48 weeks.

Introduction

Methods and sample size

Baseline

Assessment of changes in non-HDL cholesterol, fasting plasma triglycerides, non-HDL-C/HDL-C ratio, fasting glucose concentration and weight, and body mass index (BMI) were conducted in 107 subjects in Stage 1. Subjects in Stage 2 were selected according to the group-sequential design.

Endpoints and sample size

Results

Table 1. Baseline Characteristics

Table 2. Subject Disposition at 24 Weeks

Table 3. Adjusted Mean Change from Baseline in Non-HDL Cholesterol (mmol/L) at Week 24 - Repeated Measure Mixed Model Analysis

Table 4. Efficiency at Week 24

Table 5. Most Frequent ADRs by Relative Risk

Table 6. Trends in Clinical Chemistry Parameters of Special Interest

Discussion

Conclusions

Acknowledgments

References