Phase 2 Study of Fingolimod Efficacy and Safety in Japanese Patients

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INTRODUCTION AND PURPOSE

Fingolimod (FTY720) is a sphingosine-1-phosphate receptor modulator for treatment of relapsing forms of multiple sclerosis (MS). Fingolimod has demonstrated efficacy and safety in placebo-controlled trials in patients with relapsing MS worldwide.1,2

The effects of fingolimod in Japanese patients with relapsing MS have not been well characterized. A phase 2 study of fingolimod in Japanese patients with relapsing MS was conducted to assess the efficacy and safety of fingolimod in Japanese patients with MS.

METHODS

Patients

Patients were 18–65 years of age, had a diagnosis of relapsing or secondary progressive MS, and had a confirmed relapse in the prior 12 months. Patients were treated with fingolimod 0.5–1.5 mg daily or placebo for 48 weeks. Efficacy and safety measures were performed, and a 6-month follow-up was conducted.

Study design and analysis

A single-center, randomized, double-blind, placebo-controlled, parallel-group study was conducted. Patients were randomly assigned 1:1 to fingolimod 0.5 mg or 1.5 mg or placebo once daily for 48 weeks. Patients were evaluated at baseline and at months 3, 6, 9, and 12.

Safety measures

Patients were evaluated for safety every 4 weeks during the study.

Efficacy measures

The primary efficacy measure was the proportion of patients with no new or recurrent 10-point increase in EDSS over 12 months.

RESULTS

Demographic and clinical characteristics

A total of 129 patients were enrolled in the study. Of these, 127 patients completed the 48-week study (64 from the fingolimod 0.5 mg group and 63 from the placebo group). The mean age of the patients was 53 years (range, 22–77 years), and 61% were female. The mean duration of disease was 16 years (range, 1–49 years). The baseline EDSS score was 3.6 (range, 0–10). The mean number of relapses in the 12 months prior to study entry was 0.09 (range, 0–12). The mean number of new or worsened disabilities during the 12 months prior to study entry was 0.09 (range, 0–8).

Safety and tolerability

The most common adverse events (AEs) reported during the study were nasopharyngitis (28% in the fingolimod 0.5 mg group and 30% in the placebo group), fatigue (17% in the fingolimod 0.5 mg group and 19% in the placebo group), and headache (9% in the fingolimod 0.5 mg group and 10% in the placebo group). No deaths occurred during the study.

CONCLUSIONS

Fingolimod demonstrated a demonstrated efficacy and safety in Japanese patients with relapsing MS. Patients receiving continuous fingolimod therapy for 12 months showed improved or sustained MRI and relapse activity during months 7–12 compared with months 0–6.

Patients switching from placebo to fingolimod during 6 months achieved substantial reductions in clinical and MRI assessments of inflammatory activity after 6 months of fingolimod treatment.

Fingolimod was generally well tolerated with a safety profile consistent with that observed in previous studies.

REFERENCES