Efficacy and Safety of Gemcabene as an Additional Statin Therapy in Patients with Hypercholesterolemia

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Abstract

The primary study endpoint was mean percent change in LDL-C from baseline to Week 8. The endpoint was evaluated using an analysis of covariance (ANCOVA) model with effects due to treatment arm, study sites, and baseline LDL-C value as covariates. Adjusted mean changes from baseline were calculated, and results were compared in a 5% level of significance. To adjust for multiple comparisons, a step-down approach to testing was used. Treatment by-site and treatment by-sex interactions were tested separately. The Shapiro-Wilk test determined if the normality assumption was satisfied. Changes from baseline were compared by t-test for paired observations or repeated measures analysis of variance (ANOVA) for multiple measurements. The normality assumption was tested by the Shapiro-Wilk test. Results were considered significant if p < 0.05.

Methods

Sixty-one patients completed the study: 39 patients (64.1%) in the placebo group, 12 patients (19.7%) in the 300 mg group, and 10 patients (16.2%) in the 900 mg group. Sixty-two adverse events (AEs) were reported by 34 patients (55.6%). The most frequently occurring adverse events (AEs) were headache (4 patients, 6.6%) and infection (4 patients, 6.6%) in the gemcabene-treated group and infection (3 patients, 5.0%) in the placebo group. The most common treatment-emergent adverse events were headache and dizziness (2 patients each, 3.3%) in the gemcabene-treated group and 4.8% in the placebo group. No patient was withdrawn for an AE associated with treatment. Three patients (2 placebo and 1 gemcabene) withdrew due to AE(s), all of which were considered possibly related to treatment. These were no deaths in this study. Changes in clinical laboratory assessments were small, nonsignificant and generally within normal limits compared to the baseline values. The study was not double-blind; thus, the possibility of a placebo effect cannot be excluded.

Conclusions

Gemcabene 300 and 900 mg produced a mean change in LDL-C of -23.4 ± 5% (p = 0.005) and -27.7 ± 4% (p < 0.001) compared to -0.7 ± 4% with placebo. Mean (SE) percent change in LDL-C from baseline to Week 8 was significantly lower for gemcabene 300 mg and 900 mg compared to placebo (p = 0.006 and p < 0.0001, respectively).