



E1689

JACC March 27, 2012

Volume 59, Issue 13



Prevention

EFFICACY AND SAFETY OF THE CHOLESTERYL ESTER TRANSFER PROTEIN INHIBITOR ANACETRAPIB AS MONOTHERAPY AND COADMINISTERED WITH ATORVASTATIN IN JAPANESE PATIENTS WITH DYSLIPIDEMIA

ACC Moderated Poster Contributions
McCormick Place South, Hall A
Sunday, March 25, 2012, 9:30 a.m.-10:30 a.m.

Session Title: Prevention: Clinical: Current Research in Lipidology

Abstract Category: 9. Prevention: Clinical

Presentation Number: 1190-533

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Background: High-density lipoprotein cholesterol (HDL-C) levels are inversely associated with cardiovascular risk. Cholesteryl ester transfer protein (CETP) inhibition is one strategy for increasing HDL-C. This study evaluated the effects of the CETP inhibitor, anacetrapib, on lipids and safety when administered as monotherapy or in combination with atorvastatin in Japanese patients with dyslipidemia.

Methods: A total of 407 Japanese patients with dyslipidemia were randomized equally to one of 10 groups: 5 groups received background statin therapy of atorvastatin 10 mg and 5 did not, and each of these was randomized to placebo, anacetrapib 10, 40, 100, and 300 mg once daily for 8 weeks. An equal proportion of patients had triglycerides > 150 mg/dL in each group.

Results: For the placebo and anacetrapib monotherapy groups (10, 40, 100, and 300 mg), least squares mean percent changes from baseline to week 8 for low-density lipoprotein cholesterol (LDL-C) were 3%, -12%, -27%, -32%, and -32%, respectively, and for HDL-C were 1%, 56%, 116%, 134%, and 159%, respectively ($P < .001$ vs. placebo for all doses). Coadministration of anacetrapib with atorvastatin produced significant incremental LDL-C reductions and similar HDL-C increases versus anacetrapib monotherapy. Anacetrapib was well tolerated as monotherapy or when coadministered with atorvastatin 10 mg, and the dose-dependent relationships in adverse events were not observed across all treatment groups. Changes from baseline in blood pressure and electrolytes were not significantly different from placebo (for monotherapy arms) or atorvastatin 10 mg (for co-administration arms).

Conclusions: Anacetrapib, as monotherapy or coadministered with atorvastatin, produced significant reductions in LDL-C and increases in HDL-C; treatment with anacetrapib + atorvastatin produced a ~64% lowering of LDL-C and more than doubling of HDL-C. Anacetrapib was generally well tolerated, with no discernable effect on blood pressure in Japanese patients with dyslipidemia.