Effects of MAT9001, an Omega-3 Fatty Acid Drug, Compared with Eicosapentaenoic Acid Ethyl Esters, on Triglycerides, Lipoprotein Cholesterol and Related Variables in Hypertriglyceridemic Subjects

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Background
- Elevated triglycerides (TG), defined as a fasting TG concentration ≥150 mg/dL, affects approximately 23% of the US adult population (1).
- Several omega-3 fatty acid (OM3) concentrate pharmaceutical agents have been under investigation as an adjunct to statins for lowering CVD event risk in patients with high TG.

Methods
- Exclusion criteria included:
  - Abnormal or clinically significant vital signs measurements;
  - Hemoglobin <13.5 g/dL for males or <12.0 g/dL for females;
  - Very high TG: ≥500 mg/dL.

Objective
- This was an open-label, randomized, crossover trial. A sample of 42 men and women received 4 g/d MAT9001 and EPA-EE in random order, for 14-day treatment periods, separated by ≥35 days of wash-out (refer to Figure 1 for study design).

Subjects
- Eligible subjects were men and women 18-70 years of age with a body mass index (BMI) of 19.0-40.0 kg/m², who were light smokers (<10 cigarettes/day), non-smokers, with fasting TG 200-400 mg/dL without lipid-altering therapy, or non-smokers, with fasting TG <200 mg/dL, on no lipid-lowering therapy, with high TG.

Results
- Subjects who had a low TG ≥4 to 6-fold higher with MAT9001 on day 14 compared with EPA-EE. Between treatment p-values derived from ANCOVA models with baseline value, treatment, period, sequence, and subject effect as factors for the model (Table 2).

Conclusions
- MAT9001 was superior to EPA-EE for bioavailability of EPA, with baseline-adjusted area under the curve (AUC) and maximal concentration (Cmax) approximately 4 to 6-fold higher with MAT9001 on day 14 compared with EPA-EE.

Abbreviations
- ANCOVA: analysis of covariance
- CI: confidence interval
- CVD: cardiovascular disease
- IQR: interquartile range
- LDL-C: low-density lipoprotein cholesterol
- MAP: mean arterial pressure
- MAPD: mean arterial pressure decline
- OM3: omega-3 fatty acid
- SD: standard deviation
- TG: triglycerides
- HDL-C: high-density lipoprotein cholesterol
- kexin type 9 (PCSK9) levels in men and women with hypertriglyceridemia with or without statin therapy.

References

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