The Primary Results of the REDUCE-IT Trial

Purpose: to evaluate whether high-dose icosapent ethyl lowers ischemic event rates beyond statin therapy in at-risk patients

Trial Design: Phase 3b, randomized, double-blinded, placebo-controlled; median follow-up 4.5 years; . >8000 patients on statin therapy treated with icosapent ethyl 4g/day or placebo; fasting triglycerides ≥150 mg/dL and <500 mg/dL; LDL-C >40 mg/dL and ≤100 mg/dL; prior CV event or other risk factors.

Primary Endpoints: composite CVD endpoint: CV death, MI, stroke, coronary revascularization, unstable angina.

Secondary Endpoint: composite of cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke

Results: High-dose icosapent ethyl vs. placebo in at-risk patients significantly reduced the composite CVD endpoint: risk of CV death, non-fatal MI, stroke, coronary revascularization, and unstable angina needing hospitalization.

Prespecified Hierarchical Testing Results	icosapent ethyl	placebo	
Composite primary endpoint	17.2%	22.0%	25% reduction HR=0.75 P<0.001
Composite secondary endpoint	11.2%	14.8%	HR=0.74 P<0.001
Coronary revascularization	5.3%	7.8%	HR=0.65; p<0.001
MI - fatal or non-fatal	6.1%	8.7%	31% reduction HR=0.69 p<0.001
Stroke - fatal or non-fatal	2.4%	3.3%	28% reduction HR=0.72 p=0.01
CV Death	4.3%	5.2%	20% reduction HR=0.80 p=0.03
Total Mortality)	6.7%	7.6%	13% reduction HR=0.87 p=0.09

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