AEGIS-II
Effect of CSL112 on Recurrent Myocardial Infarction (MI) and Cardiovascular (CV) Death

Phase Three, Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial

OBJECTIVE: To evaluate the effects of CSL112 (Apo A-1) therapy on the incidence of CV death and recurrent MI.

18,219 PATIENTS

INCLUSION CRITERIA:
Adult patients with type 1 MI with multivessel coronary artery disease, and either drug-treated diabetes or two additional risk factors.

PRIMARY ENDPOINT
THE COMPOSITE OF CV DEATH, ALL MI OR STROKE FROM RANDOMIZATION THROUGH 90 DAYS vs. PLACEBO.
4.9% (CSL112) vs. 5.2% (PLACEBO) (HR, 0.93, P=0.24)

SECONDARY ENDPOINTS
ANALYSIS OF THE INDIVIDUAL COMPONENTS OF THE PRIMARY ENDPOINT THROUGH 90 DAYS, 180 DAYS AND 365 DAYS.
THE INCIDENCE OF CV DEATH OR ANY MI WAS NUMERICALLY LOWER IN THE CSL112 GROUP THROUGHOUT THE FOLLOW-UP PERIOD: HR, 0.91, 0.89 AND 0.92, RESPECTIVELY.

CONCLUSION
Although the primary endpoint findings were neutral, data suggest that treatment with CSL112 is well tolerated and may result in lower rates of CV death and MI.


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