The Safety and Tolerability of CSL112, a Reconstituted, Infusible, Human ApoA-I, After Acute Myocardial Infarction - The ApoA-I Event Reduction in Ischemic Syndromes I (AEGIS-I) Trial

Purpose: To evaluate the hepatic and renal safety of CSL112 used in patients with recent MI in addition to standard of care.

Trial Design: Phase 2b, multicenter, placebo-controlled, randomized trial; 16 countries; 188 sites. N=1258. 1:1:1 randomization to 4 weekly infusions of either placebo, low dose CSL112 (2 g/dose), or high dose CSL112 (6 g/dose).

Primary Safety Endpoint: Hepatic (increase in ALT, total bilirubin) or renal toxicity (increase in serum creatinine)

Trial Results	Liver				Kidney			
CSL112	2 gm dose		6 gm dose		2 gm dose		6 gm dose	
	1.0%	P=0.12	0.5%	P= 0.50	0.0%	P=0.50	0.7%	P=0.62
Placebo	0.0%				0.2%			

Conclusions: In AMI patients, CSL112 was well-tolerated; renal and hepatic function changes compared to placebo was not significant.

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