



ASX Announcement

For immediate release

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CSL Therapy That Mimics “Good” Cholesterol May Reduce Plaque Volume in Coronary Arteries

CSL Limited today announced results from a study published in the *Journal of the American Medical Association* that suggest infusions of a novel new drug, CSL-111, to acutely raise HDL (“good” cholesterol) levels, may reduce the amount of plaque in the coronary arteries of patients with a recent episode of acute coronary syndrome (ACS).

CSL advised that the Effect of Reconstituted HDL on Atherosclerosis – Safety and Efficacy (ERASE) trial was a phase 2, randomized, blinded, placebo-controlled study conducted at 17 sites throughout Canada and coordinated by the Montreal Heart Institute. The trial examined whether 4 infusions of CSL-111, given at weekly intervals to patients with a recent episode of ACS, could reduce the volume of plaque in the coronary arteries. Assessment of the arteries was performed using intravascular ultrasound (IVUS) and quantitative coronary angiography (QCA) before and 2-3 weeks after the treatment. IVUS is a technique in which a tiny ultrasound probe is inserted into the coronary arteries to determine the change in plaque during treatment. Coronary angiography is an X-ray examination of the blood vessels.

Dr Andrew Cuthbertson, CSL’s Chief Scientific Officer, advised that 183 patients had received placebo (n=60), 40 mg/kg (n=111) or 80 mg/kg (n=12) of CSL-111. He noted that the higher dosage of CSL-111 was discontinued early because of transient liver function test abnormalities, but the 40mg/kg dose was safe and generally well tolerated.

CSL confirmed that the results were based on data from 145 patients who had 2 sequential IVUS procedures. The main findings were that there was a reduction in coronary plaque volume after infusions of CSL-111 of 3.4 percent and after placebo of 1.6 percent, which were not statistically significantly different. However, when compared to baseline, the reduction for patients infused with CSL-111 was statistically significant ($p < 0.001$), but this was not the case in the placebo group. Other assessments of the plaque, such as characterization indexes or changes in plaque that are different than volume measurements, on IVUS and coronary score on QCA, were significantly different between CSL-111 and placebo. Interestingly, the difference in coronary score between patients that had 4 weeks of CSL-111 and those given placebo was similar to those observed after two years of statin treatment (compared with no statin).

“Overall, these results strongly suggest that CSL-111 is biologically active, and that short term infusions of CSL-111 result in a rapid, favourable effect on coronary atherosclerotic plaque,” said Dr. Tardif, Principal Investigator, Montreal Heart Institute. “These data



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strongly support the conduct of further clinical studies to assess whether CSL-111 will provide a clinical benefit to patients with ACS.”

“This study is a significant step in our development of CSL-111,” said Dr. Andrew Cuthbertson. “CSL recognizes the value that CSL-111 may provide in preventing further cardiovascular events in patients with ACS. We are committed to exploring the full therapeutic potential of this treatment and will consult with international experts to evaluate next steps.”

ACS is the term used to describe unstable angina and myocardial infarction (heart attack). It is estimated to be responsible for up to 600,000 admissions to hospital per year in the US. Despite improvements in management over many years, ten to fifteen percent of patients still experience a serious cardiovascular problem in the 12 months following an episode of ACS.

CSL-111 is a patented biologic product, consisting of apolipoprotein A-I purified from human plasma that is reconstituted to form a particle that chemically and biologically resembles human HDL. A 40 mg/kg dose of CSL-111 results in an approximately 50 percent elevation in blood HDL levels, which remain above normal for one week. It was discovered and is manufactured at CSL Behring in Switzerland.

For more information about CSL Limited, visit www.csl.com.au

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