

CSL releases positive data for potential new heart attack therapy and announces next phase of clinical development

Study results presented at the American Heart Association 2013 Scientific Session

Dallas, Texas - Results of a phase 2a trial of CSL112 in patients with stable cardiovascular disease have shown a dramatic and rapid increase in key indicators of reverse cholesterol transport, a process by which cholesterol is removed from arteries and transported to the liver for clearance. Rapid removal of cholesterol following a heart attack may be a new mechanism for stabilising vulnerable plaque lesions and lowering the high risk of subsequent attacks.

CSL112 is a novel formulation of apolipoprotein A-I (apoA-I), the active component of high-density lipoprotein (HDL) or 'good cholesterol'. It is purified from human plasma and reconstituted to form HDL particles suitable for intravenous infusion.

The Phase 2a study was a randomized, multicenter, double-blind, placebo-controlled trial that evaluated the effects of a single-dose administration of CSL112 in 44 patients over a 90 day period. In addition to positive results for key biological indicators, the trial data also demonstrated favourable safety and tolerability for this potential new therapy and have given CSL confidence to proceed to a phase 2b study.

"Patients who experience an acute coronary event have a high risk of suffering another heart attack, stroke or other cardiovascular event, particularly within the first 30 days", said Dr Andrew Cuthbertson, Chief Scientist for CSL.

"The results of this clinical study of CSL112 support our continued enthusiasm for its development as a novel approach to address this important treatment void."

CSL has announced a global phase 2b clinical trial program which will include sites in Australia. The trial will seek to assess multiple dose administration of CSL112 compared with placebo in approximately 1,200 heart attack patients. The final design of the trial is currently being reviewed by regulators.

Professor Philip Aylward, Cardiologist at the South Australian Health and Medical Research Institute and Director of Medicine, Cardiac and Critical Care at Flinders Medical Centre, will lead the Australian arm of the study which will involve a number of sites nationally.

"We know there is a need for better approaches to reduce the high risk of early recurrent cardiovascular events after a heart attack", said Professor Aylward.

"CSL112 is a promising treatment targeting the unstable coronary plaques causing these events and deserves further investigation."

CSL112 was developed by CSL scientists in Australia and other global sites and has benefitted from collaborations with a number of medical research institutions including the Baker IDI Heart & Diabetes Institute in Melbourne, Australia.

Professor Bronwyn Kingwell, Head of Metabolic and Vascular Physiology at the Baker IDI Institute, has been leading investigations over the last eight years into the therapeutic strategy of infusing reconstituted HDL.

“Based on our human studies there is good reason to believe that this therapeutic approach will support both cholesterol removal from plaques and their stabilization. Such actions would likely reduce the risk of plaque rupture and heart attack”, said Professor Kingwell.

“Australia has outstanding medical research institutions and hospitals and we are very pleased to be able to continue the development of CSL112 here”, said Dr Cuthbertson.

“Researchers at the Baker IDI Institute contributed important knowledge in the early development of this novel therapy and now Australian hospitals and patients will help us determine whether it is a viable treatment for the prevention of recurring heart attacks.”

There are currently no available therapies to reduce the incidence of early recurrent events by directly acting on coronary plaque before it ruptures.

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