CSL Limited Launches AEGIS-I, a Phase 2b Clinical Study of CSL112, a Novel Apolipoprotein A-I Infusion Therapy Designed to Rapidly Remove Cholesterol from Arteries and Stabilize Plaque

CSL112 Represents a Promising Investigational Therapy That May Fill a Void in Reducing Early Recurrent Cardiovascular Events in Patients Who Have Suffered a Heart Attack

King of Prussia, PA, USA – CSL Limited today announced the launch of AEGIS-I, a Phase 2b clinical study of CSL112, a novel formulation of apolipoprotein A-I (apoA-I). Administered as a short series of weekly infusions, CSL112 is designed to rapidly remove cholesterol from the arteries and stabilize lesions at risk of rupture. This represents a new approach to reduce the high incidence of early recurrent cardiovascular events in the days and weeks following a heart attack.

"Patients are at highest risk of experiencing a recurrent cardiovascular event in the first 30 days following the index event and physicians have few treatment options to address this risk," said C. Michael Gibson, M.S., M.D., Professor of Medicine at Harvard Medical School and AEGIS-I Study Chairman. "CSL112 holds the potential to work quickly to reduce early recurrent events, thereby addressing a substantial unmet medical need."

AEGIS-I is a Phase 2b, global, randomized, placebo-controlled, dose-ranging study investigating the safety and tolerability of multiple dose administration of CSL112 in 1,200 patients who experienced an acute myocardial infarction or heart attack. Secondary outcome measures include time-to-first occurrence of a major adverse cardiovascular event (MACE) defined as cardiovascular death, myocardial infarction (MI), ischemic stroke and hospitalization for unstable angina. Results of the study are expected in 2016.[i]

"We are excited to advance the clinical development program for CSL112 with the launch of the AEGIS-I study which will investigate the safety and efficacy of CSL112 administered in the post MI setting," said Denise D'Andrea, Senior Global Clinical Program Director Cardiovascular Therapies Clinical Development.

"AEGIS-I will also allow us to select the dose to take into the phase 3 outcomes trial where we will test the hypothesis that rapid removal of cholesterol with CSL112 will stabilize plaque and thereby reduce the incidence of early recurrent cardiovascular events."

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About Coronary Heart Disease

Coronary heart disease stems from problems related to plaque buildup in the walls of the arteries, a condition known as atherosclerosis. As plaque builds up, the arteries narrow, making it more difficult for blood to flow and creating a risk for heart attack or stroke.

Despite advances in therapy, coronary heart disease remains a leading cause of death globally. In the US alone:

- There are 515,000 new heart attacks and 205,000 recurrent heart attacks annually
- One heart attack occurs every 44 seconds
- 1 in 6 deaths is due to coronary heart disease

About CSL112

CSL112 is a novel formulation of apolipoprotein A-I (apoA-I), the primary functional component of high-density lipoprotein (HDL). It is purified from human plasma and reconstituted to form HDL particles suitable for intravenous infusion. Studies have shown that the infusion of CSL112 rapidly elevates markers of reverse cholesterol transport, a process by which cholesterol is removed from arteries and transported to the liver for clearance. CSL112 may offer a novel option for rapidly stabilizing atherosclerotic lesions and is being studied for reduction in the risk of early atherothrombotic events in acute myocardial infarction patients.

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[i] ClinicalTrials.gov. Identifier NCT02108262. Accessed October 13, 2014.

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