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ASX Announcement

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CSL Announces Top-line Results from the Phase 3 AEGIS-II Trial Evaluating the Efficacy and Safety of CSL112

CSL Limited (ASX:CSL; USOTC:CSLLY) today announces that it has received the top-line results from the Phase 3 AEGIS-II trial evaluating the efficacy and safety of CSL112 (apolipoprotein A-I [human]) compared to placebo in reducing the risk of major adverse cardiovascular events (MACE) in patients following an acute myocardial infarction (AMI).

The study did not meet its primary efficacy endpoint of MACE reduction at 90 days. As a result, there are no plans for a near-term regulatory filing. There were no major safety or tolerability concerns with CSL112.

C. Michael Gibson, M.S., M.D., Baim Institute for Clinical Research, Harvard Medical School and Lead Investigator for AEGIS-II said, “We look forward to sharing our scientific learnings regarding cholesterol efflux and recurrent cardiovascular events. We will continue to analyse the findings and share the full results in the coming months.”

Further analysis of AEGIS-II is ongoing and primary results will be presented at the American College of Cardiology Scientific Sessions to be held on 6 April 2024, and published in a peer-reviewed journal.

Dr Bill Mezzanotte, Executive Vice President, Head of R&D, for CSL, said: "Substantial work remains to fully analyse and understand the complete data and then to determine any development path ahead for this asset. We thank all the patients, families, caregivers, and investigators for their support and participation in the AEGIS program.

"AEGIS-II is the most ambitious study in our company’s history and we are proud of the quality of the study we delivered and the enhanced capabilities we developed to do so. We plan to apply these capabilities as well as our plasma protein platform to future unmet medical need in cardiovascular and metabolic conditions as well as those in our other strategic therapeutic areas.”

Investors will be aware that CSL has excluded any financial contribution from CSL112 in its forward-looking estimates and statements. Further, CSL does not expect any material financial impact following the AEGIS-II trial conclusion.

Half year results call for investors

CSL’s Executive VP & Head of Research & Development, Dr Bill Mezzanotte will join Dr Paul McKenzie, Chief Executive Officer and Managing Director and Joy Linton, Chief Financial Officer at the half year results briefing at 11am on Tuesday 13 February to discuss CSL112 and the topline results of AEGIS-II.

The webcast can be accessed at https://investors.csl.com/ Following the event a recording will be uploaded to the company website.

About AEGIS-II

The AEGIS-II trial is a Phase 3 multicenter, double-blind, randomized, placebo-controlled, parallel-group study which evaluated the efficacy and safety of CSL112 in the reduction of recurrent cardiovascular events in the 90-day high-risk period that follows a heart attack. The study enrolled over 18,200 patients from over 850 sites in 49 countries. Participants were randomized to receive 4 weekly doses of CSL112 or placebo initiated within 5 days of first medical contact.

About CSL112

CSL112, Apolipoprotein A-I (Human), is an investigational cholesterol efflux enhancer, developed using a novel formulation of human plasma-derived apoA-I, the primary functional component of high-density lipoproteins (HDL).

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