



ASX Announcement

For immediate release

16 November 2016

CSL Behring Presents Positive Results from CSL112 Phase 2b Trial

CSL Limited (ASX:CSL; USOTC:CSLLY) - At the American Heart Association (**AHA**) Scientific Sessions in New Orleans, Louisiana, held on 15 November 2016, CSL Behring announced positive results from AEGIS-I, a Phase 2b safety and proof of mechanism clinical study of CSL112, a novel apolipoprotein A-I (**apoA-I**) infusion therapy. CSL112 is being developed to reduce the high incidence of early recurrent cardiovascular events that frequently occur in the weeks to months following a heart attack, most commonly due to additional rupture of vulnerable atherosclerotic plaque. The results have been published online in [Circulation](#) (the AHA's Scientific Journal).

The AEGIS-I study met its co-primary safety endpoints, showing that CSL112 does not cause significant changes in liver or kidney function and demonstrating that it is well-tolerated when administered in the post myocardial infarction (**MI**) (or heart attack) setting. The study also provided confirmation of CSL112's unique mechanism of action, cholesterol efflux enhancement, as demonstrated by an immediate, up to four-fold increase in cholesterol efflux capacity, compared to baseline. It is believed that by producing an immediate and profound enhancement of cholesterol efflux capacity, which is the removal of cholesterol from the plaque in the arteries, CSL112 may rapidly stabilize additional lesions at risk of rupture thereby reducing the high rate of recurrent events following a heart attack.

"We are highly encouraged by the impressive results of this clinical study demonstrating that CSL112 significantly increases cholesterol efflux capacity in patients who have suffered a heart attack, with no significant changes to liver or kidney function," said Larry Deckelbaum, Global Clinical Therapeutic Area Head, Cardiovascular at CSL Behring. "The AEGIS-I results support continued planning for Phase 3 to determine whether increasing cholesterol efflux capacity with CSL112 translates into improved cardiovascular outcomes."

In the US alone, approximately 750,000 heart attacks occur every year¹. For those patients who survive, the risk is not over. Approximately one in five will experience a recurrent cardiovascular event within one year, most of those events occur very early - approximately half within the first month, and recurrent events are associated with worse

¹ American Heart Association. Heart Disease and Stroke Statistics—2016 Update. *Circulation*. 2015;132:000-000. DOI: 10.1161/CIR.0000000000000350



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clinical outcomes.²³⁴ By rapidly removing cholesterol from plaque following a heart attack, CSL112 may help to stabilize dangerous lesions in the arteries that could otherwise erupt and cause another cardiovascular event.

About CSL112

CSL112 is a novel formulation of plasma-derived apoA-I, the primary functional component of HDL, and is being developed by CSL Behring, in collaboration with its parent company, CSL Limited. CSL112 is reconstituted to form HDL particles suitable for intravenous infusion. Studies have shown that infusion of CSL112 rapidly elevates markers of cholesterol efflux capacity, a process by which excess cholesterol is removed from plaque and transported to the liver for elimination from the body. CSL112 may offer a novel option for rapidly stabilizing atherosclerotic plaque lesions and is being developed for reduction in the risk of early cardiovascular events in acute MI patients.

About CSL

CSL is a leading global biotherapeutics company with a dynamic portfolio of life-saving innovations, including those that treat haemophilia and immune deficiencies, as well as vaccines to prevent influenza. Since our start in 1916, we have been driven by our promise to save lives using the latest technologies. Today, CSL — including our two businesses CSL Behring and Seqirus — operates in over 30 countries with more than 16,000 employees. Our unique combination of commercial strength, R&D focus and operational excellence enables us to identify, develop and deliver innovations so our patients can live life to the fullest. For more information, please visit www.csl.com.au.

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² Jernberg T, et al. Cardiovascular risk in post-myocardial infarction patients: nationwide real world data demonstrate the importance of a long-term perspective. *Eur Heart J*. 2015;36:1163-1170.

³ Kohli P et al. Reduction in First and Recurrent Cardiovascular Events With Ticagrelor Compared With Clopidogrel in the PLATO Study. *Circulation* 2013;127:673-680

⁴ Shotan A, et al. Comparison of Outcome of Recurrent Versus First ST-Segment Elevation Myocardial Infarction (from National Israel Surveys 1998 to 2006). *Am J Cardiol*. 2011;107:1730-1737.