<table>
<thead>
<tr>
<th>STUDY TITLE</th>
<th>The AEGIS II Study: A Phase 3. Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome.</th>
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<tbody>
<tr>
<td>STUDY POPULATION</td>
<td>Patient with Acute Coronary Syndrome</td>
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<tr>
<td>PRINCIPAL INVESTIGATOR</td>
<td>Dato’ Sri Dr. Haji Azhari Rosman</td>
</tr>
</tbody>
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| STUDY COORDINATOR | Noor Syamira Mokhtar  
Contact number : 03 – 2617 8200 Ext: 3133 |
| START DATE | 01 October 2018 |
| END DATE | 30 September 2020 |
| INCLUSION | - Capable of providing written informed consent and willing and able to adhere to all protocol requirements.  
- Male and female at least 18 years of age at the time of providing written consent.  
- Evidence of myocardial necrosis in a clinical setting consistent with type I (spontaneous) MI as define by the following:  
  a) Detection of a rise and/or fall in cardiac troponin I or T with at least 1 value above the 99th percentile upper reference limit  
- AND With any 1 or more of the following:  
  a) Symptoms of ischemia (ie, resulting from a primary coronary artery event)  
  b) New (or presumably new) significant ST/T wave changes or left bundle branch block.  
  c) Development of pathological Q waves on electrocardiogram.  
  d) Imaging evidence of new loss of viable myocardium or regional wall motion abnormality.  
  e) Identification of intracoronary thrombus by angiography.  
- No suspicion of AKI at least 12 hours after IV contrast agent administration (subject who have undergone angiography) or after FMC for the index MI (subject who have not undergone angiography). There must be documented evidence of stable renal function defined as no more than increase in serum creatinine <0.3mg/Dl (~27µmol/L) from pre-contrast serum creatinine value.  
- Evidence of multivessel coronary artery disease defined as meeting 1 or more of the following criteria:  
  a) At least 50% stenosis on >1 epicardial artery or left main artery on catheterization performed during the index hospitalization.  
  b) Prior cardiac catheterization with at least 50% stenosis on >1 epicardial artery or left main artery  
  c) Prior PCI and evidence of at least 50% stenosis of at least 1 epicardial artery different from prior revascularized artery.  
  d) Prior multivessel coronary artery bypass grafting. |
- At least 1 of the following established risk factors:
  a) Age ≥ 65 years.
  b) Prior history of MI
  c) On pharmacological treatment for diabetes mellitus.
  d) Peripheral arterial disease defined as meeting at least one of the following criteria:
     i. Current intermittent claudication or resting limb ischemia AND an ankle brachial index ≤ 0.90
     ii. History of peripheral revascularization (surgical and percutaneous)
     iii. History of limb amputation due to peripheral arterial disease.
     iv. Angiographic evidence (using computed tomographic angiography, magnetic resonance angiography, or invasive angiography) of a peripheral artery stenosis ≥ 50%
- Female subjects must be postmenopausal or with a negative urine pregnancy test prior to randomization. If the urine test cannot be confirmed as negative, a serum pregnancy test will be required.
  a) Postmenopausal status is defined as subjects over the age of 60 years, subjects aged 45 to 60 years (inclusive) with amenorrhea for at least 1 year with documented evidence of follicle-stimulating hormone level >30 IU/L, or subjects who are surgically sterile for at least 3 months before randomization. If the follicle-stimulating hormone value is not available prior to randomization, a urine test is required.
  b) Females of childbearing potential must be willing to use an acceptable method of contraception to avoid pregnancy during the study and for 30 days after receipt of the last dose of investigational product; and, if currently breastfeeding a child, willing to cease breastfeeding.
- Investigator believes that the subject is willing and able to adhere to all protocol requirements.
- Willing to not participate in another investigational study until completion of their final study visit.

**EXCLUSION**

- Ongoing hemodynamic instability defined as any of the following:
  a) A history of NYHA Class III or IV HF within last year.
  b) Killip Class III or IV
  c) Sustained and/or symptomatic hypotension (systolic blood pressure <90mmHg)
  d) Known left ventricular ejection fraction <30%
- Evidence of hepatobiliary disease as indicated by any 1 or more of the following at screening:
- Current active hepatic dysfunction or active biliary obstruction.
- Chronic or prior history of cirrhosis or of infectious/inflammatory hepatitis
- ALT > 3X upper limit of normal (ULN) or total bilirubin > 2X ULN at time of randomization. Subjects with a known or suspected history of Gilbert’s syndrome are not eligible for study participation if their direct bilirubin is > 2X ULN.
- Evidence of severe chronic kidney disease with an estimated glomerular filtration rate of < 30ML/min/1.73m² (as calculated by the Chronic Kidney Disease Epidemiology Collaboration equation) or if subject is receiving dialysis.
- Body weight < 50kg
- Known history of allergies, hypersensitivity, or deficiencies as follows:
  a) Allergy to soy bean or peanut
  b) Known or suspected hypersensitivity to the investigational product, or to any excipients of the investigational product or placebo (albumin
  c) A known history of IgA deficiency or antibodies to IgA
- Other severe comorbid condition, concurrent medication, or other issue that renders the subject unsuitable for participation in the study, including but not limited to:
  a) A comorbid condition with an estimated life expectancy of ≤ 6 months at the time of consent.
  b) Women who are pregnant or breastfeeding at the time of randomization.
  c) Participated in another interventional clinical study within 30 days of consent or has plans to participate in another clinical study at the time of consent.
  d) Known alcohol, drug, or medication abuse within 1 year before consent to this study.
  e) Treatment with anticancer therapy (chemotherapy, immunotherapy, radiology, targeted therapy, or gene therapy) within 3 months before the first administration of investigational product or at any time during the study. Recovery from associated toxicities (eg, hematologic) must be documented in the source document
  f) Previously randomized or participated in the study or previously exposed to CSL 112.
  g) Mental condition rendering the subject (or the subject’s legally acceptable representative) unable to understand the nature, scope, and possible consequences of the study
  h) Subjects who are incarcerated, including prisoners or subjects compulsorily detained for treatment of either a psychiatric or physical (eg, infectious disease) illness.
i) Inability or unwillingness to comply with all follow up through end of the study, and/or unwilling to allow review of medical records in accordance with local regulatory requirements at the time of consent.

j) Investigator determines that the subject is not suitable for study participation for any other reason.

- Involved in the planning and/or conduct of the study (applies to CSLB staff, staff at the study site, and third-party vendors)