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Patient Care + Research + Clinical Trials

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VEGF-inhibition with CSL346 in DKD

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Summary:
Patients with established DKD will enter into a 34 weeks RCT in which they will be assigned (1:1:2) to receive blinded CSL346 (8 mg/kg CSL34**Study location** BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W26, 16 mg/kg CSL346, or placebo).

Hypothesis: Vascular Endothelial Growth Factor (VEGF) is involved in the development and progression of diabetic kidney disease (DKD). Blockade of VEGF-B activity leads to the prevention of toxic lipid accumulation in the kidney. CSL346, the investigational product (IP), is a monoclonal antibody (mab) molecule that antagonizes VEGF-B, is hypothesized to slow the rate of loss of renal function via pathways other than those impacted by either RAS or SGLT2 inhibition.

Eligible Participants include:

- T2DM Male or female aged > 24 yrs old
- 24 hour UACR > 17 mg/mmol
- eGFR initially > 45 -60 ; then midway 20-60 eGFR will be allowed
- Stable use of ACEi or ARB

Treatment course and duration:
The study is designed as a randomized, double-blind, parallel-group, placebo-controlled study that runs for 34 weeks. It involves a 12 week treatment period followed by a 12 week follow up period. Subject's first dose of IP will be an intravenous (IV) loading dose. Subjects will receive 3 subsequent SC infusions for a total of 4 SC doses.

Odds of receiving placebo : 1:1:2 ((8 or 16 mg CSL346 or 50% Placebo)

Study documents:
Informed Consent
Protocol
Short URL = https://bit.ly/3figTTA