

## **Ustekinumab RCT- UST1D2 A Clinical phase II/III trial in newly diagnosed Type 1 diabetes aged 18-25**

**Study location:** [BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2](#)

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### **Summary:**

**UST1D2** is a phase II/III randomized controlled trial of the effectiveness of ustekinumab (drug:placebo ratio of 2:1) in newly diagnosed Type 1 diabetes aged 18-25 years.

### **Hypothesis:**

Ustekinumab delays the loss of  $\beta$ -cells and maintains a clinically relevant level of  $\beta$ -cell function in young adults with newly diagnosed with T1D.

### **Eligible Participants include:**

- Male or female aged 18-25 years at randomization diagnosed with T1D by ADA criteria.
- Ability to receive the first dose of study drug within 100 days of diagnosis of T1D.
- Positive for  $\geq 1$  T1D autoantibody (GADA, IA-2A, miAA or ZnT8A) & peak stimulated C-peptide  $\geq 0.2$  pmol/ml

### **Treatment course and duration:**

Ustekinumab or matching placebo will be administered via IV infusion at a loading dose of 6 mg/kg given at week 0. Thereafter 90 mg Ustekinumab/PBO will be given SC at weeks 8, 16, 24, 32, 40 and 48 (7 doses total). Total duration of study is 78 weeks, In order to quantitate endogenous B cell function, a 2hr MMTT will be conducted at screening , week 28, 52 and 78 for key endpoint assessment.

**Odds of receiving placebo  $\frac{1}{3}$  (33%)**

### **Other notes**

All subjects will be provided CGM (Dexcom G6) at no charge for the 18 month duration of the study. Grants to help cover the costs of accommodation & travel to Vancouver from anywhere in western Canada are available.

### **Study documents:**

[Protocol](#)

[Consent form](#)

[Ethics Approval](#) [Ethics renewal](#)

Short URL to this document: <http://bit.ly/USTT1D2>