

## **Ustekinumab RCT- UST1D2 A Clinical phase II/III trial in newly diagnosed Type 1 diabetes aged 18-35**

**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 18-35 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 18-35 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](#) (GAD65, 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, necessitating 10 trips to the site, 4 trips requiring an overnight stay. 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%)**

### **Freebies, travel and accommodation subsidies**

All subjects will be provided a CGM (Dexcom G6 or G7) at no charge for the first 12 months of the study. For Canadian residents full reimbursement for travel & accommodation expenses to Vancouver or Toronto from anywhere in Canada is available upon request.

For US or international potential participants a total subsidy for travel and accommodation of US\$4000 for the 10 trips to Vancouver (equivalent to US\$400 per trip) may be available.

### **Study documents:**

[Protocol](#) [Consent form](#) [Ethics Approval](#) [Ethics renewal](#)

[Conflict of Interest statement](#)

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