

## **OBTAIN - nanobody Rx in newly diagnosed T1D**

**T1D OBTAIN (ACT18368) Phase 2a study assessing safety and efficacy of SAR442970, a dual anti-TNF- $\alpha$  and anti-OX40L NANOBODY<sup>®</sup> molecule, for preservation of pancreatic  $\beta$ -cell function in adults and adolescents with recently diagnosed type 1 diabetes”**

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

**Principal Investigators** Drs. Tom Elliott and David Lee

**Study coordinator & primary contact** Dr. Hector Com P: 604-628-7253 x 7012 :

[hcom@bcdiabetes.ca](mailto:hcom@bcdiabetes.ca)

**Summary:** OBTAIN ( ACT 18368) is a phase 2a study RCT testing the Efficacy and Safety of SAR442970, a dual anti-TNF- $\alpha$  and anti-OX40L NANOBODY<sup>®</sup> injection given every 2 weeks in newly diagnosed T1DM patients. (drug:placebo ratio of 3:1)

**Hypothesis:** SAR442970 hopes to preserve pancreatic  $\beta$ -cell function in adults and adolescents with newly diagnosed type 1 diabetes on insulin therapy

**Eligible Participants include:**

- 18-35 yrs of age
- Newly diagnosed T1DM within 100 days of first study drug infusion
- + to 1 auto Ab (GAD65; IA-2, ZnT8, or Insulin), if obtained within 10 days of onset of exogenous insulin therapy
- C peptide  $\geq$  0.2 nmol/L (by MMTT)
- Initiated exogenous insulin replacement therapy not longer than 90 days prior to Screening

**Treatment course and duration:**

This is a randomized, placebo-controlled, parallel group, multicenter, double-blind Phase 2, 2-arm study that consists of 2 parts. Part A, to test safety of SAR442970 in adults (age range 18 to 35 y.o.) once this is established, we will transition to Part B (in adolescents and young adults, 12 to 21 y.o.) evaluating the safety and efficacy of SAR442970 in comparison with placebo in participants with newly diagnosed T1D on insulin treatment.

**Odds of receiving the new molecule :** 3:1 ( SAR442970 or placebo)

**Study documents:**

[Informed Consent Form](#)

[Protocol](#)

Short url: <https://bit.ly/OBTAIN1D>

