bcdiabetes.ca
Patient Care + Research + Clinical Trials

Dr. Tom Elliott MBBS, FRCPC
Medical Director

400 - 210 W Broadway
Vancouver, BC
V5Y 3W2 Canada

phone: 604.683.3734
fax: 604.628.3821
email: moa@bcdiabetes.ca

Lenbelintide in Participants with Type 2 Diabetes Mellitus and Obesity or Overweight (SELENE 2)

Principal Investigator: Dr. Tom Elliott **SubInvestigator**: Dr. Dale Clayton
Study coordinator & primary contact Marla Inducil MD, Hector Com MD, Glaiza Erfe MD P: 604-628-7253 x 7011, minducil@bcdiabetes.ca ; gerfe@bcdiabetes.ca; hcom@bcdiabetes.ca, amoshiri@bcdiabetes.ca

Summary: A Phase III Study to investigate efficacy and safety of lenbelintide in participants with T2DM and obesity or overweight

Study location: BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2

Background & hypothesis: Overweight and obesity are defined as a BMI of ≥ 25 kg/m2 to 30 kg/m2 or ≥ 30 kg/m2, respectively. Overweight and obesity are a risk factor for the development of numerous comorbid conditions, including metabolic-abnormality-associated steatotic liver disease, T2DM, cardiovascular disease, and chronic kidney disease. Endogenous amylin is a hormone co-secreted with insulin into the bloodstream it promotes satiation and satiety, it slows gastric emptying resulting in a reduction of food intake and reduction of blood glucose. It also enhances hypothalamic leptin signalling, which is a key pathway for the regulation of energy storage and food intake. Lenbelintide is a synthetic version of amylin that is given by injection once weekly. Lenbelintide will be studied to see whether it improved diabetes outcomes including improving sugar control and weight control without sacrificing muscle mass.

Eligible Participants include:

- **Age ≥18 yrs**
- **BMI ≥ 27 kg/m2**
- **A1c ≥ 6.0% ≤ 10% on diet and exercise alone OR on any oral hypoglycemic agent; no insulin nor GLP1**

Treatment course and duration: The total study duration for the individual participant will be approximately 74 weeks, including: • 2-week Screening period. • 16-week titration. • 52-week maintenance treatment. • 4-week SFU period (off IMP).

Odds of receiving placebo: lenbelintide (9 mg): pbo - 2:1

Procedure	Scr.	R	Titration Period [a] (16 weeks)						Treatment Period (52 Weeks)							SFU [b]	Phone Visit [c, d]	EDV [e]	Details in Section
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15 EoT [f]				
Week	-	1	2	3	4	5	9	13	17	21	25	29	41	53	69				
Day	up to -14	1	8	15	22	29	57	85	113	141	169	197	281	365	477				
Visit Window (Days)			± 3	± 3	± 3	± 3	± 3	± 3	± 5	± 5	± 5	± 5	± 5	± 5	± 5	± 3	± 3	± 3	
Fasted Visit		X							X			X			X	X		X	

Study documents:

Informed Consent

Conflict of Interest statement

Short URL = https://bit.ly/4dVEZ5Q