

AZD6234 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 AZD6234 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.

Eligible Participants include:

- Age ≥ 18 yrs
- BMI ≥ 27 kg/m²
- A1c $\geq 6.0\% \leq 10\%$ 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: AZD6234 (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	
			3	4	5	6	7	8	9	10	11	12	13	14					15 EoT ^f
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>