

## Roche dual agonist GLP1 in T2D with BMI ≥27 study

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

**Summary:** WC45726 is a Phase III, multi-center, randomized, double-blinded, placebo-controlled, parallel group study to evaluate the efficacy and safety of RO7795068, a novel unimolecular dual GLP-1/GIP RA peptide at 8 mg, 16 mg, and 24 mg weekly subcutaneous doses compared with placebo, as an adjunct to a reduced-calorie diet and increased physical activity in participants with Type 2 Diabetes Mellitus (T2DM) who have obesity (body mass index ≥ 30 kg/m<sup>2</sup> or overweight (BMI ≥ 27 and < 30 kg/m<sup>2</sup>).

**Hypothesis:** RO7795068 is a novel unimolecular dual GLP-1/GIP biased agonist that activates cyclic adenosine monophosphate (cAMP) signaling but does not recruit β-arrestin or cause Ca<sup>2+</sup> release from either receptor. These signaling properties are expected to be important for the clinical benefits, which include significant weight loss and improved glycemic control.

### Eligible Participants include:

- Individuals aged ≥18 years of age
- BMI ≥27.0 kg/m<sup>2</sup>
- Diagnosis of T2DM ( HbA1c ≥6.5% < 10% ), on stable oral therapy for at least 3 months prior to screening and naive to GPL-1 and DPP-4 agents - prior use of a GLP-1 or DPP-4 agent is an exclusion
- History of one self-reported unsuccessful diet/exercise effort to lose body weight

**Treatment course and duration:** The study has a duration of 79 weeks and will include a screening period (4 weeks), a treatment period (72 weeks), and a safety follow-up period (3 weeks). The treatment period has an up-titration phase, where participants will start at 4 mg with the goal to up-titrate the dose on a monthly basis to achieve the assigned target maintenance dose (8, 16, or 24 mg) and a maintenance phase where participants will continue on their assigned target dose for the remainder of the treatment period. All enrolled participants will receive dietary and physical activity counseling every 4 weeks for the first 12 weeks, and then every 12 weeks thereafter. Participants who complete the treatment period will have the opportunity to continue in a separate long-term extension (LTE) study.

**Odds of receiving active drug = 75% (25% will receive placebo)**

Study Period	Protocol Section	Screening Period <sup>a</sup>		Treatment Period																		ED visit <sup>b</sup>	Safety Follow-up <sup>c</sup>	
		SCR1	SCR2	0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	64	68			72
Study Week		SCR1	SCR2	0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	64	68	72	within 7 days after last dose of study drug	75 (or 4 weeks after last dose of study drug)
Day(s)		-28 to -1	-14 to -1	1 <sup>e</sup>	29	57	85	113	141	169	197	225	253	281	309	337	365	393	421	449	477	505	+3	526
(Visit Window) <sup>d</sup>				±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3		+7
Fasting Visit <sup>f</sup>		x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Remote Visit <sup>g</sup>														x	x		x	x		x	x			

### Study documents:

#### Informed Consent

#### [Conflict of Interest statement](#)

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