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Patient Care + Research + Clinical Trials

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Roche dual agonist GLP1 in T2D with BMI ≥27 study

Principal Investigator: Dr. Tom Elliott **SubInvestigators**: Drs. Dale Clayton & David Lee
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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/m2 or overweight (BMI ≥ 27 and < 30 kg/m2).

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 Ca2+ 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/m2**
- **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 [a]		Treatment Period																		ED visit [b]	Safety Follow-up [c]
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 [e]	29	57	85	113	141	169	197	225	253	281	309	337	365	393	421	449	477	505		526
(Visit Window) [d]				±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	±3	+3	+7
Fasting Visit [f]		x		x	x	x	x	x	x	x	x	x	x			x			x			x	x	x
Remote Visit [g]														x	x		x	x		x	x			

Study documents:
Informed Consent
Conflict of Interest statement
Short URL https://bit.ly/48CsGIQ