bcdiabetes.ca
Patient Care + Research + Clinical Trials

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GLP1/GIP in T1DM with CKD (Roche CC46203)

Study location BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
Principal Investigators Dr. Tom Elliott
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Back up coordinators: Hector Com MD and Glaiza Erfe MD

Summary: This study will evaluate the efficacy, safety, and pharmacokinetics of RO7795074, a weekly injectable dual GLP/GIP receptor agonist, compared to placebo in T1D participants with CKD at high risk for kidney disease progression despite limited existing treatments. All participants will receive background standard of care therapy for CKD (ACEi/ARB +/- aldosterone antagonists)

Hypothesis: This study will examine the efficacy, safety, and pharmacokinetics of RO7795074 in T1D participants with CKD and an eGFR 25 to 90 mL/min/1.73 m2 and UACR 22.6-565 mg/mmol

Eligible Participants include:

- Male or female > 18 yrs of age; BMI > 23 kg/m2
- T1DM > 1 yr; A1c </= 10.5%
- eGFR >25 to < 90 mL/min/1.73 m2 at screen
- UACR >/= 22.6 to </= 565 mg/mmol at screen
- On stable ACEi or ARB
- No GLP-1 RA within 90 days of screening

Treatment course and duration: The estimated maximum study follow-up for participants is approximately 112 weeks.

Odds of receiving active drug are: 1:1 RO7795074 or placebo stratified according to UACR; A1c and SGLT2in +/-

Period	Screening[a]	Treatment Period to Week 52																	Treatment Period after Week 52[b]	EOT[c]	Safety Follow-up[c]
Week(s)	−4 to −1	Day 1	1[d]	2	3[d]	4	5[d]	6[d]	7[d]	8	10[d]	12	18	24	30[d]	36	44[d]	52	Q12W		
Visit day(s)	−28 to −1	1	8	15	22	29	36	43	50	57	71	85	127	169	211	253	309	366	+85		EOT + 4 weeks
Site Visit	x	x		x	(x)[d]	x		(x)[d]		x	(x)[d]	x	x	x		x		x	x	x	x
Fasting Site Visit		x								x			x	x		x		x		x	x
Telephone visit			TV		TV		TV	TV	TV		TV				TV		TV				
Window (days)		NA	±3								±7								±7	+7	+7

Study documents:
Protocol
Short URL = https://bit.ly/4aIBM6L