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

Roche WC45727 dual agonist GLP1/GIP in T1D with BMI ≥23 26 weeks

Principal Investigator: Dr. Tom Elliott SubInvestigators: Drs. Dale Clayton & David Lee
Study coordinator & primary contact Marla Inducil MD P: 604-628-7253 x 7011 with assistant coordinators Hector Com MD & Glaiza Erfe MD
Study location: BCDiabetes: 400 - 210 West Broadway, Vancouver V5Y 3W2
Summary: WC45727 is a Phase III, randomized, double blind, multicenter, placebo controlled study to evaluate the efficacy and safety of RO7795074 over 26 weeks in participants with Type 1 Diabetes.
Hypothesis:RO7795074, a unimolecular dual glucagon-like peptide-1 (GLP-1)/glucose-dependent insulinotropic polypeptide (GIP) receptor biased agonist, is, when used as an adjunct to insulin therapy in adults with type 1 diabetes (T1D) and a body mass index [BMI] 23 kg/m2, is expected to be well toleranced and to improve glycemic indices.

Eligible Participants include:

- **Individuals aged ≥18 years of age**
- **BMI ≥25.0 kg/m2 (Main Study Cohort); (Normal BMI Cohort) BMI 23 kg/m2 - 25.0 kg/m2 at screening and prior to randomization**
- **Diagnosis of T1DM (HbA1c ≥7%< 10.5 %), on treatment with subcutaneous daily insulin either via MDI, non-AID CSII, or AID pump, with no change in insulin method of delivery (e.g., MDI to manual or AID pump or vice versa) within the 2 months prior to screening and for the duration of the study**
- **No self-reported body weight change of 5% in the 3 months prior to screening visit**

Treatment course and duration: The study consists of 3 Periods:

Pre-treatment period: up to 28 days and will include a screening period of 14 days and a mandatory 2-week baseline run-in period.
Randomized treatment period: a 26-week randomized treatment period and a
Safety follow-up period: a 4-week safety follow-up period will follow the last dose of study treatment.

Odds of receiving active drug: in Main Study cohort = 3:1; in normal BMI study cohort = 1:1

Period	Randomized Treatment Period																			Safety Follow-Up [a]	
Week	Day 1	1	2	3	4	5	6	7	8	10	12	14	16	18	20	22	24	26	ETD [b]	27	30
Visit day (±3 days)	1	8	15	22	29	36	43	50	57	71	85	99	113	127	141	155	169	183		See footnote "a."	
Site visit (number)	3	—	4	—	5	—	6	—	7	—	8	—	9	—	10	—	—	11	—	—	15
Fasting site visit [c]	x	—	—	—	x	—	—	—	x	—	x	—		—	x	—	—	x	x	—	x
Telehealth visit [d, e]	—	x	—	x	—	x	—	x	—	x	—	x	—	x	—	x	x	—	—	x	—

Study documents:
Informed Consent
Conflict of Interest statement
Short URL = https://bit.ly/3ZuVyNV