

Maridebart Cafraglutide (Maritide) monthly vs semaglutide weekly on top of metformin +/- SGLT2 in T2D

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

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Summary: a phase 3, multicenter, randomized, active-controlled, open-label, parallel group, global trial that will compare the efficacy and safety of maridebart cafraglutide once every 4 weeks (Q4W) versus semaglutide once weekly (QW) in participants with T2DM who are inadequately controlled with metformin, +/- SGLT2i

Hypothesis: Maridebart cafraglutide (otherwise known as AMG 133) is a first-in-class, bispecific, peptide-antibody conjugate with functional activities that antagonize GIPR and agonize GLP-1R. As such, maridebart cafraglutide represents a new drug class within T2DM management, whose effects are mediated via a combined activation of the GLP-1R and GIPRi.

Eligible Participants include:

- ≥ 18 yrs of age
- BMI ≥ 25 kg/m²
- A1c ≥ 7.5 - $\leq 10\%$
- No GLP-1 RA; DPP4i within 90 days of screening
- Only metformin and SGLT2i allowed

Treatment course and duration: Eighteen visits over 76 weeks

Odds of receiving active drug are: 1:1 subjects will receive either maridebart-cafraglutide 350 mg every 4 weeks or semaglutide 2mg weekly

Procedure	Treatment Period ^a																		
Week		2	4	8 ^b	12	16	20	24 ^b	28	32	36	40 ^b	44	48	52 ^b	56	60	64 ^b	EOT ^{b,c}
Days	1 ^b	15	29	57	85	113	141	169	197	225	253	281	309	337	365	393	421	449	
Window (Days)		± 3	± 3	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	± 7	

Study documents:

Protocol :

Short URL = <https://bit.ly/4fjPArQ>