A Case Report of a Pregnant Woman with Familial Chylomicronemia Syndrome Treated With Plozasiran, a Small Interfering RNA Against ApoC3

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Disclosure Slide

x	No, nothing to disclose
	Yes, please specify:

Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Royalties/ Patent*	*Stock Options*	*Ownership/ Equity Position*	*Employee*	*Other (please specify)*

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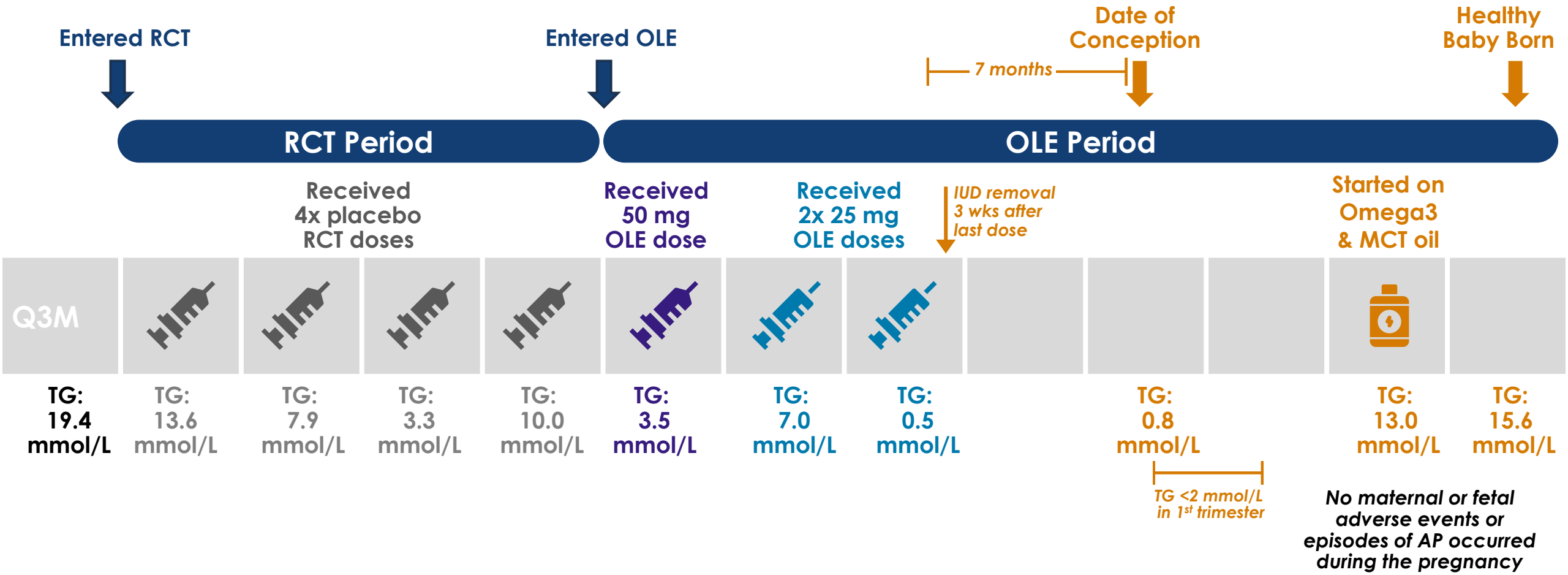
Introduction

- Familial chylomicronemia syndrome (FCS) is characterized by markedly elevated fasting triglyceride (TG) levels (>10 mmol/L) and is associated with a high risk of acute pancreatitis (AP)[1]
- More pronounced increases in TG levels have been reported in women with FCS during pregnancy, increasing the risk of AP[1]
- Plozasiran (REDEMPLO), a GalNAc conjugated small interfering RNA targeting apolipoprotein CIII (ApoCIII) dosed every 3 months, is FDA approved as an adjunct to diet to reduce triglycerides in adults with FCS and has received a positive CHMP opinion in the EU
  - Currently in clinical development for the treatment of severe hypertriglyceridemia
- This is the second case report of a pregnancy associated with the PALISADE study, the first resulted in delivery of a healthy baby[2]
- Data on exposure are insufficient to inform the safety and efficacy during pregnancy

1. Al-Shali K, et al. Clin *Biochem*. 2002;35:125–130. **2.** Larouche M, et al. *JIMD Reports*; 2025; 67(1):e70052.

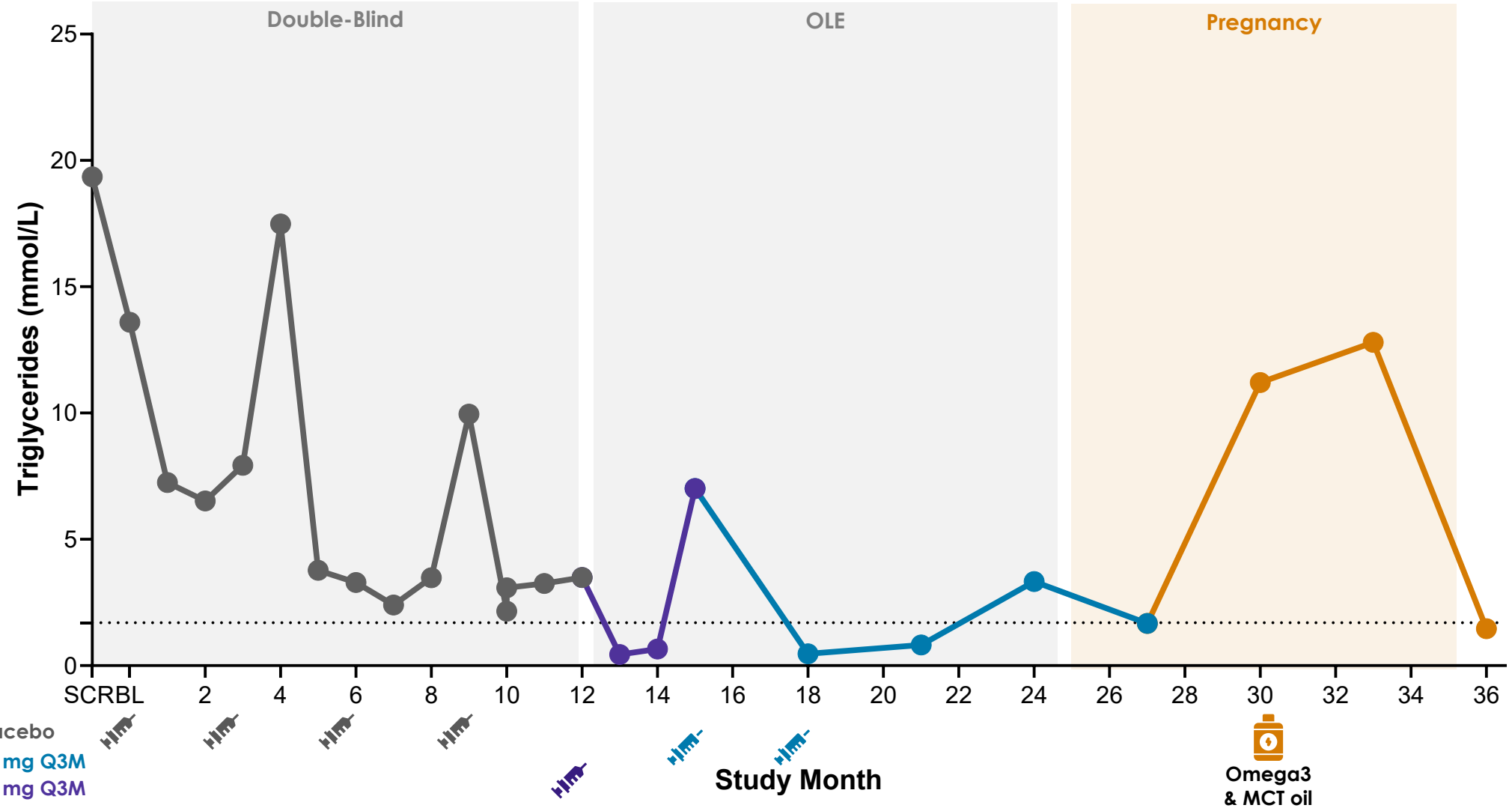
Case Description: 28-year-old Woman with Genetically Confirmed FCS

History of 1 prior AP event prior to start of study



AP, acute pancreatitis; **FCS**, familial chylomicronemia syndrome; **MCT**, medium-chain triglyceride; **OLE**, open-label extension; **Q3M**, every 3 months; **RCT**, randomized control trial; **TG**, triglycerides.

Triglyceride Levels Over Course of PALISADE Study and Pregnancy



BL, baseline; **OLE**, open-label extension; **MCT**, medium-chain triglyceride; **Q3M**, every 3 months.

Safety Data Measures

	Study Baseline	Month 12	OLE Dose 1	OLE Dose 2	OLE Dose 3	Pre-pregnancy	Post-pregnancy
Glucose (mmol/L)	4.3	4.7	—	4.8	—	4.5	3.7
HbA1c (%)	4.9	5.3	5.3	5.5	5.1	5.2	4.9
HOMA-IR	0.71	0.68	—	1.8	—	0.5	0.42
ALT (U/L)	13	15	18	13	15	14	7
AST (U/L)	16	18	17	14	17	18	14
Lipase (U/L)	21	26	—	31	17	21	33

No maternal or fetal adverse events or episodes of AP occurred during the pregnancy

The baby was born full term with a normal APGAR with a birth weight reported as 3.2 kg (7.1 lbs) and length of 50 cm (19.7 in) which are within the normal ranges.

ALT, alanine aminotransferase; **APGAR**, appearance, pulse, grimace, activity, and respiration; **AST**, aspartate aminotransferase; **HbA1c**, glycated hemoglobin; **HOMA-IR**, Homeostatic Model Assessment for Insulin Resistance; **OLE**, open-label extension.

Conclusion

Clinical Challenge: Pregnancies in patients with FCS are associated with a high and often recurrent risk of AP, particularly in later trimesters, with the potential for serious maternal and fetal complications; accordingly, TG levels should be monitored as a dynamic risk marker requiring close and sustained control.[1-3]

- This case suggests that preconception exposure to plozasiran may be associated with sustained lowering of fasting TG levels throughout the term of a pregnancy, consistent with the prolonged pharmacodynamic effects of ApoCIII inhibition reported in PALISADE, yet without any evident adverse maternal or fetal complications.
- This is the second case report of a pregnancy associated with the PALISADE study, the first also resulted in delivery of a healthy baby, suggesting that plozasiran administration a few weeks before pregnancy in women with FCS may lower TG levels.[4]
- Additional data are needed to define the safety and efficacy of ApoCIII–targeted therapies during pregnancy.

1. Larouche et al. *JCEM*. 2026;11:e455–e461. **2.** Gupta et al. *Am J Med*. 2022;135(6):709-714. **3.** Cruciat et al. *Lipids Health Dis*. 2020;19(1):2. **4.** Larouche M, et al. *JIMD Reports*; 2025; 67(1):e70052.
AP, acute pancreatitis; **ApoCIII**, apolipoprotein-C III; **FCS**, familial chylomicronemia syndrome; **TG**, triglycerides.