

Australia approves small interfering RNA medicine for Familial Chylomicronemia Syndrome

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Arrowhead Pharmaceuticals receives TGA approval of REDEMPLO® (plozasiran) in Australia



US-based Arrowhead Pharmaceuticals has announced that the Australian Therapeutic Goods Administration (TGA) has approved REDEMPLO® (plozasiran), a small interfering RNA (siRNA) medicine, as an adjunct to diet to reduce triglyceride levels for adult patients with familial chylomicronemia syndrome (FCS) for whom standard triglyceride lowering therapies have been inadequate.

FCS is a severe, rare disease characterised by triglyceride levels that can be orders of magnitude higher than normal, leading to a substantially higher risk of developing acute, recurrent, and potentially fatal pancreatitis. FCS remains widely underdiagnosed and affects an estimated 1 to 13 people per million globally.

REDEMPLO is the first and only medicine approved for use in the treatment of FCS in Australia, and is authorised for both genetically confirmed and clinically diagnosed adult patients with FCS.

This approval by TGA follows approvals in the United States, Canada, and China, and a positive opinion recommending marketing authorisation from EMA as Arrowhead continues its efforts to increase global access to care for people living with FCS.

Harnessing Arrowhead's proprietary Targeted RNAi Molecule (TRiM™) platform, REDEMPLO is designed to silence the mRNA encoding apolipoprotein C-III (apoC-III). ApoC-III is a key regulator of triglyceride metabolism that inhibits triglyceride catabolism and clearance, resulting in elevated triglyceride levels. Individuals with genetic loss-of-function variants in APOC3 typically have markedly lower triglyceride levels and a reduced risk of atherosclerotic cardiovascular disease.