Evaluation of the Dual PPAR-α/γ Agonist Aleglitazar to Reduce CV Events in Patients with ACS and Type 2 Diabetes Mellitus: the AleCardio Trial

History: Secondary prevention for acute coronary syndrome (ACS) patients includes the need for control of lipid and glucose levels – both a challenge for those who also have type 2 diabetes. Aleglitazar is a peroxisome proliferator-activated receptor (PPAR) agonist that has demonstrated effective insulin and glucose balancing actions as well as positive effects on lipid levels.

Questions to answer: Is aleglitazar efficacious and safe when used in addition to standard care for reducing cardiovascular (CV) morbidity and mortality in ACS patients with type 2 diabetes?

Trial Design	Phase III, randomized, double-blind, parallel, two-arm study N~7,220 patients in 26 countries randomized 1:1 to 150 mg/day aleglitazar in morning or placebo
Primary Endpoints	Efficacy: Time to CV death, non-fatal CV event (myocardial infarction or stroke) Safety - hospitalization for heart failure or renal function
Trial Results	• Trial was ended early due to higher incidence of adverse events (heart failure, renal dysfunction, bone fractures, GI hemorrhage, and hypoglycemia) in the aleglitazar group. • No significant difference in the primary endpoint was observed between groups (HR 0.96, 95% CI 0.83-1.11, P=0.57). • The aleglitazar group did see improved levels of triglycerides and HDL-C and reductions in glycated hemoglobin.

Take Away: Aleglitazar in addition to standard care did not reduce CV risk in ACS patients with type 2 diabetes. Results support the need for more research in the development of PPAR activating drugs.

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