

Amgen sees inclisiran threat and seeks new Repatha patients



[Jonathan Gardner](#)

How worried is Amgen about the potential for the Medicines Company’s twice-a-year cholesterol-lowering injection inclisiran to steal market share from Repatha? Worried enough that it is willing to initiate a new clinical trial, costing hundreds of millions of dollars, to break into a new market – prevention of cardiovascular events in high-risk patients who have not already had one. Earlier this week the group registered the new study with clinicaltrials.gov, and the filing reveals that the trial will enrol 13,000 patients with cardiovascular disease and elevated LDL, and follow them for four years. Composite endpoints measuring cardiovascular death, myocardial infarctions, strokes and revascularisation will be evaluated. In terms of patient numbers and outcomes, the new Amgen trial looks similar to the Medicines Company’s Orion-4 cardiovascular outcomes study, although that phase III trial reserves inclisiran for patients who have already experienced a myocardial infarction, stroke or peripheral artery disease. Amgen also thinks it can generate outcomes data by mid-2024 – six months earlier than Orion-4 – and thus be able to counter a potential marketing push against Repatha, as well as Sanofi and Regeneron’s Praluent, by the Medicines Company in the post-event population. The new Amgen trial may cost around \$800m, according to an estimate using EvaluatePharma Vision’s R&D Cost methodology.

Comparing the cardiovascular outcomes studies			
	Repatha		Inclisiran
	Fourier	VESALIUS-CV	Orion-4
Population	High-risk cardiovascular disease patients post-MI, stroke or peripheral artery disease	High-risk cardiovascular disease patients without prior MI or stroke	High-risk cardiovascular disease patients post-MI, stroke or peripheral artery disease
Enrolment	27,564	13,000	15,000
Endpoint	Cardiovascular death, MI, stroke, revascularisation or hospitalisation for unstable angina	Cardiovascular death, MI, stroke or revascularisation	Cardiovascular death, MI, stroke or revascularisation
Completion	Nov 2016	May 2024	Dec 2024
Trial ID	NCT01764633	NCT03872401	NCT03705234

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