

Merck leads the new cholesterol-lowering push



[Madeleine Armstrong](#)

[Promising data on Merck & Co's oral PCSK9 inhibitor](#) MK-0616 – plus [impressive late-stage results](#) with its pulmonary arterial hypertension project sotatercept – added nearly \$11bn to the group's market cap yesterday. And a look at the PCSK9 pipeline shows Merck is well ahead of its oral rivals. Indeed, one of these recently dropped out, with Novo Nordisk quietly discontinuing NN6435 in the third quarter of last year following phase 2 data. At the time of publication, a spokesperson had not responded to questions about the reasons behind this decision. If eventually approved, Merck's MK-0616 could take market share from currently approved monthly injectable PCSK9 inhibitors from Amgen and Sanofi/Regeneron, as well as Novartis's twice-yearly therapy Leqvio. But others are going even longer acting, with a couple of gene editing contenders in early-stage development. [Since the last time Evaluate Vantage carried out this analysis](#), however, one of these has also fallen by the wayside: Precision Biosciences said in January that it was [ceasing development of PBGENE-PCSK9](#). A previous update noted that the group's partner Iecure, which had been responsible for a phase 1 study, had not completed IND-enabling activities; the deal was signed in September 2021.

Selected PCSK9-targeting projects in development

Project	Company	Description	Note
Phase 2			
MK-0616	Merck & Co	Once-daily oral	Ph2 data at ACC 2023, ph3 planned in H2 2023
Phase 1			
AZD0780	Astrazeneca	Oral	NCT05384262 in healthy volunteers; data due H2 2023
VERVE-101	Verve Therapeutics	One-off in vivo gene editing	Heart-1 enrolling in New Zealand & UK, first data due H2 2023; US IND on clinical hold
Preclinical			
VXX-401	Vaxxinity	"Long-acting" synthetic peptide vaccine; target 2-4 per year	Preclinical data at ACC 2023 ; ph1 slated for H1 2023
CTX330	Crispr Therapeutics	One-off in vivo gene editing	
STP135G	Sirnaomics	SC RNAi	
Fallen by the wayside			
ION449 (AZD8233)	Astrazeneca/Ionis	Once-monthly SC antisense	Astra not taking into ph3 following ph2 Solano data
NN6435/NNC0385-0434	Novo Nordisk	Oral	Company had ph2 data in Q3 2022; no longer in pipeline
PBGENE-PCSK9	Precision Biosciences/Iecure	One-off in vivo gene editing	Discontinued at preclinical stage

Source: Evaluate Pharma & [clinicaltrials.gov](#).

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