

Novo seeks a cardiovascular boost



[Elizabeth Cairns](#)



An outcomes trial could increase demand for Wegovy even further - if pricing, and production, can be worked out.

Data from Mounjaro's pivotal trial in obesity, [released in April](#), make Lilly's incretin look better than its forerunner, Novo Nordisk's Wegovy, once again. But a readout is coming that could provide a massive boost for Novo's product.

Select, the vast trial assessing Wegovy's effect on cardiovascular outcomes among patients with obesity, is expected to yield data this summer. A hit could provide even more reason for doctors to prescribe the therapy - though with Novo already struggling to meet demand, it could be some time before the Danish group sees the effects.

More bullish Novo backers had hoped that Select would be stopped early for efficacy. This did not transpire, with the data monitoring committee saying that the trial should continue to its final readout. Novo's shares fell 13% on the news, suggesting that some might be worried about the trial hitting at all, but that announcement coincided with [Novo delaying the full launch](#) of Wegovy, which will also have contributed to the share price drop.

Semaglutide, the molecule approved as Wegovy in obesity, is also approved as Ozempic in type 2 diabetes, and here it [already carries a cardioprotective claim on its label](#).

This is based on the Sustain-6 trial, in which the agent significantly reduced the occurrence of major adverse cardiovascular events by 26% over placebo. Mace was defined as the time to first occurrence of a composite of cardiovascular death, non-fatal heart attack and non-fatal stroke.

The endpoint of Select is identical, and Select is powered to show a 17% relative Mace reduction, though statistical significance can still be achieved a little below this. Some analysts have suggested that a 20% improvement over placebo would be regarded as highly successful. But background use of statins and blood pressure drugs, used more commonly in obesity than diabetes, could lower events relative to Sustain-6. And if the 17% benchmark is missed, investors are likely to be disappointed.

Price

Price is already an issue, with US pricing arbiter Icer [determining last year](#) that the health-benefit benchmark for semaglutide was \$7,500 to \$9,800 per year, around half its current cost. Maybe a cardioprotective claim in obesity could help loosen payers' purse strings.

As ever, though, Lilly is close behind. Its rival product, the GIP/GLP-1 agonist Mounjaro, has outperformed Ozempic and Wegovy in just about every important setting so far. Thus the possibility that it will show a greater cardiovascular benefit than Novo's products cannot be discounted.

Its outcomes trial in diabetes, Surpass-CVOT, ought to report next year, though it may be hard to compare the relative risk reductions with Wegovy's diabetes outcomes trial, Sustain-6, since Surpass-CVOT uses Trulicity as its control rather than placebo.

Data from Mounjaro's outcomes study in obesity could arrive in 2027. If Select hits, Novo will have just four years or so to capitalise on this advantage. But of course Novo has another problem – it is still unable to produce semaglutide in large enough quantities to meet even current levels of demand. Select succeeding could be almost moot if Novo cannot open enough factories.

Novo's Ozempic/Wegovy vs Lilly's Mounjaro - CV outcomes trials				
Project and dose	Ozempic 0.5-1.0mg	Wegovy 2.4mg	Mounjaro, unknown dose(s)	Mounjaro, up to max tolerated dose
Trial	Sustain-6 (NCT01720446)	Select (NCT03574597)	Surpass-CVOT (NCT04255433)	Surmount-MMO (NCT05556512)
Population	Vs pbo in 3,297 pts w type 2 diabetes	Vs pbo in 17,500 pts with overweight or obesity	Vs Trulicity in 12,500 pts with type 2 diabetes	Vs pbo in 15,000 pts w obesity
Results	At 2.1 years, MACE rate was 6.6% with semaglutide vs 8.9% w pbo; HR 0.74	DMC recommended trial continue Q4 2022; full data due mid-2023	PCD Oct 2024	PCD Oct 2027

PCD=primary completion date. Source: company communications, NEJM.

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