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Novo fights back

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A day after Lilly's strong clinical showing in obesity, Novo comes out swinging.

The best defence is offence, they say. Certainly Novo Nordisk seems to be living by this maxim, today unveiling a punchy upgrade to its full-year 2022 guidance on the back of its obesity and diabetes franchises, and defending Wegovy against Lilly's potential challenger tirzepatide.

On a call this afternoon Novo's chief executive, Lars Fruergaard Jørgensen, pointed out that its obesity therapy had sold DKr1.4bn ($198m) "without promotion and with very limited supply capacity". He added that in his opinion there had been "a bit too much focus on comparing two trials and what I think is a relatively modest difference in weight loss".

The strength of Novo's sales in obesity and diabetes, led by Wegovy and Ozempic respectively, allowed it to substantially raise its guidance for 2022. Its sales outlook was lifted from 6-10% to 10-14%, and operating profit growth upped from 4-8% to 9-13%.

Novo's management is correct in that it would be premature to write the Danish group off, as impressive as yesterday's data on Lilly's tirzepatide were. Firstly Novo has a sizeable head start: Wegovy was approved in the US last summer. Doctors were already familiar with the drug in its guise as the diabetes therapy Ozempic, which reached the market in 2017.

The importance of this market occupancy was underlined by Lilly's handbrake turn over filing. The group had previously said it would wait for full data from tirzepatide's Surmount programme in obesity, due in a year or so, before going to regulators. It now hoping to fast-track approval for tirzepatide, with the aim of cutting into Novo's dominance as soon as possible.

Secondly, the battle will be as much about tolerability as anti-obesity efficacy. Though tirzepatide looks less toxic than Wegovy so far, a lot more data are still due from the Surmount studies. Neither drug is particularly clean, and if patients have to take them chronically to maintain weight loss any advantage on side effects will become hugely important.

Efficacy in another sense will come back into play soon enough. Novo is running Select, a trial looking at Wegovy's potential to improve cardiovascular outcomes in more than 17,000 obese patients. An interim analysis could come next quarter, with final data due next year, and a hit on hard endpoints like heart attack and stroke could change the game, and help strengthen arguments for the drug's use.

Tirzepatide is also in a CV outcomes trial, albeit in the diabetes setting. Surpass-CVOT uses Trulicity, which has a proven cardioprotective effect, as a control, and should report in 2024.

Combos

Competition in the future will also be about the various next-gen compounds the two groups are pursuing.

Novo is working on cagrisema, a combination of Wegovy with an amylin analogue currently in phase 2 for diabetes and phase 1 for obesity. This is to enter a phase 3 obesity study this year, with Novo looking for weight loss of 25% or more.

Lilly has it own long-acting amylin agonist, which it has just moved into phase 1; the long-term plan here is to combine it with tirzepatide. Yesterday's data suggest that if it comes down to adding amylin to the obesity therapies, Lilly could have the better backbone for such a combo.

Still, the obesity space is certainly large enough to support both Wegovy and tirzepatide, and any combinations that come behind them. Novo has the first-mover advantage, but it will have to work hard to defend it.

Selected upcoming trials from Novo and Lilly

Company	Project	Trial name	Details	N	Results
Novo Nordisk	Wegovy	Select	CV outcomes in patients with overweight or obesity	17,500	Interim data Q3 2022
Lilly	Tirzepatide	Surpass-CVOT	CV outcomes in patients with type 2 diabetes, vs Trulicity	12,500	PCD Oct 2024
Lilly	Tirzepatide	Surmount-1	Vs pbo in obesity or overweight pts	2,539	Hit
Lilly	Tirzepatide	Surmount-2	Vs pbo in obesity or overweight pts w type 2 diabetes	900	Expected Q2 2023
Lilly	Tirzepatide	Surmount-3	Vs pbo in obesity or overweight pts after a lifestyle weight loss programme	800	Expected Q2 2023
Lilly	Tirzepatide	Surmount-4	Vs pbo in obesity or overweight pts - maintenance of weight loss	750	Expected Q2 2023
Novo Nordisk	Cagrisema	Unnamed	Phase 3 trial in obesity to start Q4 2022	Unknown	Unknown
Source: Evaluate Pharma, clinicaltrials.gov.					