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Pricing questions remain as Novo gets the nod for oral sema



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Novo Nordisk says that oral semaglutide’s list price will be “similar” to Ozempic’s, but it will be a while before its true cost becomes apparent.

In one of the biggest approval decisions of the year, Novo Nordisk’s oral version of semaglutide has got the US green light. But big questions still hang over the drug, now branded Rybelsus, including whether it will get a label for cardiovascular risk reduction, and how much it will really cost.

On the latter, all Novo is saying is that Rybelsus’s US list price will be “similar” to that of its once-weekly injectable sema, Ozempic. However, this is before taking rebates into account, and the post-rebate price tag might not become apparent until sales figures emerge next year.

Currently, *EvaluatePharma* sellside consensus forecasts Rybelsus’s 2024 revenues at \$3.3bn; the drug’s ultimate price will be an important factor in whether it meets these expectations and becomes one of the biggest products launched in 2019.

Top five drug launches in 2019, by 2024 sales

Company	Product	Indication; description	Approval date	Annual sales (\$m)		
				2020e	2022e	2024e
Abbvie	Skyrizi	Psoriasis; anti-IL-23 MAb	Apr 2019	678	2,122	3,726
Novo Nordisk	Rybelsus	Diabetes; oral GLP1 agonist	Sep 2019	393	1,749	3,335
Abbvie	Rinvoq	Rheumatoid arthritis; Jak1 inhibitor	Aug 2019	347	1,608	3,054
Alexion Pharmaceuticals	Ultomiris	PNH; anti-complement factor C5 MAb	Dec 2018	949	1,814	2,470
Novartis	Zolgensma	SMA; gene therapy	May 2019	1,060	1,861	1,933

Source: EvaluatePharma.

At least investors now have an idea, albeit a rough one, of Rybelsus's cost, which will be in line with Ozempic's list price of \$26 per day. Before the approval, Bernstein analysts [had speculated](#) that Rybelsus would be slightly cheaper, at \$20-22 per day.

The post-rebate price tag will be another story. For injectables this is around \$15-17 per day, and oral sema might need to come in lower than this to capture market share and compete with other, less expensive branded oral diabetes drugs like the SGLT2 inhibitors. Continued pricing pressure in the US diabetes market will not help Novo, either.

Bernstein analysts believe the actual price of Rybelsus could go as low as \$10 per day, though they conceded that this was on the low side of expectations.

Novo's chief scientific officer, Mads Krogsgaard Thomsen, would not be drawn on the company's rebating plans, telling *Vantage* that the group was only just starting negotiations with payers. But he said that a comparable price to that of injectables was justified by Rybelsus's clinical performance, as well as improved adherence with oral drugs.

Novo needs to pull off a delicate balancing act if it is to launch Rybelsus without cannibalising Ozempic too much. During a conference call today the group's chief financial officer, Karsten Munch Knudsen, contended that there should be "plenty of space" for both products, given that Rybelsus's main rivals will be other oral diabetes drugs; however, he admitted that there would be some impact on Ozempic.

The picture is further complicated by the expected entrance in 2024 of generic versions of Victoza, Novo's once-daily injectable GLP1. The company will have to hope that convenience wins out, but it seems likely that generics will hit the entire class.

Cardiovascular decision coming

Meanwhile, Novo is due a decision from the FDA in January on the cardiovascular indication for both Rybelsus and Ozempic, based on pooled data from the Pioneer 6 and Sustain 6 studies ([Novo's next big diabetes bet heads to regulators](#), November 26, 2018).

The trials found a respective 21% and 26% reduction in major adverse cardiovascular events with semaglutide versus placebo. But Pioneer 6 showed non-inferiority, not superiority, while Sustain 6 did not include a prespecified superiority analysis – hence the pooling of the data.

So it is far from clear whether either drug will get the cardiovascular go-ahead next year, and Novo might have to wait for data from bigger cardiovascular outcomes trials such as the 9,600-patient [Soul study](#) of Rybelsus, which began earlier this year.

This is not set to complete until 2024, but an interim analysis could provide a chance for an earlier win. Exactly when this happens will depend on how quickly Novo can recruit patients and how soon events occur; all Mr Thomsen would say was that recruitment was "going well".

Starting Soul before getting a cardiovascular decision looks like an expensive – but probably necessary – insurance policy. *EvaluatePharma Vision's* R&D cost model estimates that Soul will set Novo back around \$300m.

Another big opportunity for Novo is obesity, where the [Select cardiovascular outcomes trial](#) of Ozempic is

ongoing. A more immediate indication of whether the product has a future here will come with data from [Step 1](#), the first trial in the pivotal Step programme, next year.

Selected semaglutide outcomes trials					
Project	Trial	Description	N	Trial ID	Primary completion
Rybelsus	Soul	CV outcomes in T2DM and heart disease	9,642	NCT03914326	Jul 2024
Ozempic	Step 1	Weight loss in overweight/obese pts	1,950	NCT03548935	Mar 2020
	Step 2	Weight loss in T2DM non-insulin pts	1,210	NCT03552757	Mar 2020
	Step 3	Weight loss with Ozempic plus intensive lifestyle programme	611	NCT03611582	Mar 2020
	Step 4	Weight loss maintenance	902	NCT03548987	Feb 2020
	Select	CV outcomes in obesity and CV disease	17,500	NCT03574597	Sep 2023
	Flow	Cardiorenal outcomes in T2DM and chronic kidney disease	3,160	NCT03819153	Aug 2024
	Focus	Eye outcomes in T2DM and diabetic retinopathy	1,500	NCT03811561	Feb 2025

Source: EvaluatePharma, [clinicaltrials.gov](#).