

## Novo Sustains momentum with first weekly GLP-1 data



[Jonathan Gardner](#)

Positive data from semaglutide's first pivotal trial is in line with rising expectations for Novo Nordisk's next GLP-1 agonist.

Although Sustain 1 tested the once-weekly injection against placebo in never-treated diabetics only, its effects on blood sugar and weight loss are good signs that it will continue to perform well in comparative studies against other agents – most importantly AstraZeneca's Bydureon. Success across the 8,000-patient programme is essential for Novo to protect its share of the GLP-1 market.

### Good start

Semaglutide lowered patients' glycated haemoglobin (HbA1C) levels from a mean of 8.1% at the beginning of the trial by 1.5 percentage points in patients treated with a 0.5mg dose and by 1.6 percentage points in patients treated with 1mg, Novo reported. Of the patients taking the 0.5mg dose, 74% achieved a goal of lowering HbA1C to below 7%, compared with 73% in the 1mg group. Weight loss of 3.8kg and 4.6kg on average were recorded from a baseline mean of 92kg.

Patients taking placebo saw no mean change in HbA1C, achieved the 7% goal in 25% of cases and saw weight loss of 1kg on average. The HbA1C change and weight loss endpoints were judged statistically superior for semaglutide. Adverse events were consistent with Novo's once-daily Victoza, and were largely related to nausea and other gastrointestinal side effects that diminished over time.

This population most likely is not one that necessarily would be prescribed semaglutide immediately – generic metformin or sulfonylureas are often go-to drugs for newly diagnosed patients. Other on-patent oral drugs that typically have better tolerability are frequently prescribed before physicians turn to the GLP-1 class.

But for investors this was an early sign that semaglutide would measure up – shares rose 2% to DKr 39.20 in mid-afternoon trading following Friday's post-market data release. Novo's first GLP-1, Victoza, quickly seized the bulk of the market when it launched in 2009, helped along by head-to-head data showing superior blood-sugar control over the first once-weekly, Bydureon. However, that lead is slipping away with the entry of new competitors – most significantly, another once-weekly in Eli Lilly's Trulicity.

### Rising star

Semaglutide's forecasts have been edging up in recent months as analysts have gained confidence in its chance of success ([Event – Novo looks to Sustain GLP-1 leadership with semaglutide, January 21, 2015](#)). The *EvaluatePharma* consensus stands at \$810m in 2020, a forecast that has risen from \$588m since the start of the year.

If that comes to pass, Novo's GLP-1 franchise – which also includes Xultophy, a combination of Victoza with the long-acting insulin Tresiba – could hold its market share just about steady at 62%. That is admittedly down from the 73% share Victoza alone held in 2013, but under current forecasts its share declines to 40%. Trulicity's share is estimated to rise to 12%, and would most likely increase further without the semaglutide challenge.

Seven more trials are due to read out between now and early 2016, all of them more revealing in terms of semaglutide's likely use in clinical practice. Aside from the Sustain 3 head-to-head against Bydureon, comparisons to Merck & Co's pill Januvia and Sanofi's long-acting insulin Lantus will be essential to assessing Novo's commercial promise. And of course, the big 3,300 patient Sustain 6 outcomes trial will need to show no signs of long-term cardiovascular impairment – shortcomings in outcomes data derailed Tresiba two years ago in the US, and the FDA's views on Novo's new submission will be the biggest event of 2015 for Novo.

Semaglutide's performance, however, will be as closely watched. Investors will be keen for Novo to retain its leadership in the one segment it dominates, and the new data will demonstrate whether, and by how much, semaglutide can help.

## Semaglutide pivotal programme

Acronym	Enrollment	NCT ID	Setting
Sustain 1	387	NCT02054897	vs placebo in treatment naïve patients
Sustain 2	1,200	NCT01930188	vs Januvia as an add-on to metformin and/or TZD
Sustain 3	798	NCT01885208	vs Bydureon as add-on to 1-2 oral antidiabetic drugs
Sustain 4	1,047	NCT02128932	vs Lantus as add-on to metformin, with or without sulfonylurea in insulin-naïve patients
Sustain 5	397	NCT02305381	vs placebo as an add-on to basal insulin, with or without metformin
Sustain 6	3,297	NCT01720446	Long-term cardiovascular outcomes trial

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