company announcement

Once-weekly semaglutide 2.0 mg demonstrates superior reduction in HbA_{1c} vs once-weekly semaglutide 1.0 mg in people with type 2 diabetes in the SUSTAIN FORTE trial

Bagsværd, Denmark, 17 November 2020 - Novo Nordisk today announced headline results from the SUSTAIN FORTE trial, a phase 3b 40-week, efficacy and safety trial with once-weekly semaglutide 2.0 mg vs once-weekly semaglutide 1.0 mg as add-on to metformin and/or sulfonylureas in 961 people with type 2 diabetes in need for treatment intensification. The trial achieved its primary endpoint by demonstrating a statistically significant and superior reduction in HbA_{1c} at week 40 with semaglutide 2.0 mg compared to semaglutide 1.0 mg.

When evaluating the effects of treatment taken as intended[1] and from a high mean baseline HbA_{1c} of 8.9%, people treated with semaglutide 2.0 mg achieved a statistically significant and superior reduction in HbA_{1c} of 2.2% compared with a reduction of 1.9% with semaglutide 1.0 mg at week 40. The American Diabetes Association (ADA) treatment target of HbA_{1c} below 7.0% was achieved by 68% of people treated with semaglutide 2.0 mg vs 58% on semaglutide 1.0 mg.

From a mean baseline body weight of 99.3 kg, people treated with semaglutide 2.0 mg experienced a statistically significant[1] and superior weight loss of 6.9 kg compared with 6.0 kg with semaglutide 1.0 mg.

When applying the treatment policy estimand[2], people treated with semaglutide 2.0 mg experienced a reduction in HbA_{1c} of 2.1% compared to 1.9% for people treated with 1.0 mg dose at week 40. People treated with semaglutide 2.0 mg experienced a statistically non-significant weight loss of 6.4 kg compared with 5.6 kg with semaglutide 1.0 mg.

[1] Based on the trial product estimand: treatment effect if all people adhered to treatment and did not initiate other type 2 diabetes therapies

[2] Based on the treatment policy estimand: treatment effect regardless of treatment adherence or initiation of other type 2 diabetes therapies

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	Trial product estimand[1]		Treatment policy estimand[2]	
Once-weekly semaglutide	2.0 mg	1.0 mg	2.0 mg	1.0 mg
HbA_{1c} reduction	2.2%*	1.9%	2.1%*	1.9%
Body weight reduction	6.9 kg*	6.0 kg	6.4 kg	5.6 kg

*Statistically significant vs once-weekly semaglutide 1.0 mg

In the trial, both doses of semaglutide appeared safe and well-tolerated. The most common adverse events were gastrointestinal, the vast majority were mild to moderate and diminished over time and were consistent with the GLP-1 receptor agonist class. Compared to semaglutide 1.0 mg, the gastrointestinal adverse events were similar for semaglutide 2.0 mg with nausea rates around 15% for both doses. The treatment discontinuation rates due to adverse events were similar and below 5% for both doses of semaglutide.

"We are very pleased with the results from the SUSTAIN FORTE trial with the large HbA_{1c} reduction from a high baseline as well as the safety and tolerability profile, which establish a attractive benefit-risk ratio for treatment of type 2 diabetes with semaglutide" said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk. "Semaglutide 1.0 mg has across the SUSTAIN programme demonstrated that up to 80% of patients achieved HbA_{1c} levels below 7%. This study demonstrates that patients in poor glycaemic control increase the likelihood of achieving their HbA_{1c} target when treated with semaglutide 2.0 mg."

About the SUSTAIN clinical programme
The SUSTAIN clinical development programme for once-weekly subcutaneous semaglutide injection currently comprises 11 phase 3 global clinical trials, including a cardiovascular outcomes trial, involving more than 11,000 adults with type 2 diabetes in total. Semaglutide 1.0 mg is approved under the brand name Ozempic® indicated for type 2 diabetes.

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 44,000 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

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