

company announcement

Novo Nordisk announces positive results for phase 2 trial with oral semaglutide in people with type 2 diabetes

Bagsværd, Denmark, 20 February 2015 – Novo Nordisk today announced that it has successfully completed the phase 2 trial for OG217SC; an oral formulation of the long-acting GLP-1 analogue semaglutide, investigating dose range, escalation, efficacy and safety of once-daily oral semaglutide compared with oral placebo or once-weekly subcutaneously administered semaglutide in around 600 people with type 2 diabetes treated for 26 weeks.

From a mean baseline HbA_{1c} of 7.9%, people treated with oral semaglutide in five different doses ranging from 2.5 mg to 40 mg achieved dose-dependent improvements in HbA_{1c} of 0.7% to 1.9% after 26 weeks. By comparison, people treated with a dose of 1 mg subcutaneous semaglutide or placebo achieved improvements of 1.9% and 0.3% respectively. Confirming the primary end-point of the trial, all doses of oral semaglutide were statistically significantly superior to placebo.

Furthermore, from a mean baseline weight of 92 kg, people treated with subcutaneous semaglutide experienced a weight loss of around 6.5 kg, which was comparable to the weight loss experienced by the people treated with the highest doses of oral semaglutide. People treated with placebo experienced a weight loss of just over 1 kg.

In the trial, semaglutide appeared to have a safe and well-tolerated profile. The most common adverse events were related to the gastrointestinal system, primarily nausea and vomiting, and diminished over time. The gastrointestinal adverse events appeared to be dose-dependent and were more prevalent for the highest doses of oral semaglutide compared to subcutaneous semaglutide. No other apparent differences between the treatment groups were observed with respect to overall adverse events and standard safety parameters.

“We are very pleased with the results of this trial confirming the potential of semaglutide to treat type 2 diabetes, both as a once-weekly subcutaneous injection and as a once-daily tablet”, said Mads Krosgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. “This clinical proof of concept marks an important milestone for oral peptide therapy within the field of diabetes”.

