press release

# Switching to Ozempic® from another GLP-1 RA significantly reduced blood sugar and weight in people with type 2 diabetes in routine clinical practice

- A separate real-world study showed that people with type 2 diabetes on two oral antidiabetic drugs who intensified with a glucagon-like peptide-1 receptor agonist (GLP-1 RA) were significantly more likely to reach their blood sugar goals and lose weight compared to adding a further oral antidiabetic drug(s) or insulin.[1]

**Bagsværd, Denmark, 13 June 2020 –** Novo Nordisk today announced results from two real-world studies: EXPERT, which confirms the efficacy Ozempic® (once-weekly semaglutide) demonstrated in the SUSTAIN clinical trial programme, and PATHWAY, which supports recommendations in clinical guidelines by showing that initiation of a GLP-1 receptor agonist (GLP-1 RA) helps people with type 2 diabetes reach their blood sugar goals (measured by $HbA_{1c}$) while also losing weight. These studies, which analysed data from US databases, were presented during the American Diabetes Association 80th Scientific Sessions.[1,2]

The EXPERT study showed that a switch to Ozempic® from another GLP-1 RA in people with type 2 diabetes was associated with statistically significant reductions in blood sugar and weight, independent of the previous GLP-1 RA used. After 6 months, the study showed $HbA_{1c}$ reductions of 2.2% for people with $HbA_{1c}$ levels above 9% at baseline and $HbA_{1c}$ reductions of 1.1% for those with $HbA_{1c}$ levels above 7% at baseline. These reductions were sustained after 12 months. Average weight loss of 2.2 kg was observed at 6 months, but was more pronounced with 3.5 kg at 12 months, for all participants.[2]

A second real-world study, PATHWAY, pointed to the increased effectiveness of the GLP-1 RA class compared with other oral antidiabetic drugs or insulin in people with type 2 diabetes on two oral antidiabetic drugs requiring treatment intensification. Ozempic® was not one of the GLP-1 RA treatments given at intensification because the study data were collated before Ozempic® was fully established on the US market.

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The PATHWAY study showed that intensifying treatment with a GLP-1 RA resulted in a statistically significant increased likelihood of achieving $HbA_{1c}$ below 7% and weight reduction from baseline compared with adding a further oral antidiabetic (s). These blood glucose and weight reductions were more pronounced compared with insulin intensification, where those taking a GLP-1 RA were almost twice as likely to achieve $HbA_{1c}$ below 7% and approximately three times more likely to lose weight.[1]

"GLP-1 receptor agonists have been shown to safely lower blood glucose levels and help lower weight, therefore they are recommended by all diabetes treatment guidelines as either second- or third-line treatment options in most people with type 2 diabetes," said study investigator Dr. Ildiko Lingvay, who consults for Novo Nordisk and is a Professor of Internal Medicine, and Population and Data Sciences at UT Southwestern Medical Center. "These data provide information from the real-world use of GLP-1 receptor agonists and further support the recommendations in the clinical guidelines by showing that initiation of a GLP-1 receptor agonist helps more people with type 2 diabetes reach their blood sugar goals while also helping them lose weight."

"More than half of people with type 2 diabetes do not reach their blood sugar target, yet we know that consistently poor blood sugar control can lead to serious complications," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "Real-world data is therefore essential to help physicians select optimal treatment for their patients to meet their blood sugar goals, and it is reassuring to see from the EXPERT study that the efficacy Ozempic® demonstrated in the SUSTAIN Phase 3 clinical trial programme is reflected in routine clinical practice."

Whilst real-world evidence generates valuable insights about the effectiveness of a medicine in a real-life setting, there are also limitations. Real-world studies may be subject to bias and confounding factors, aspects that are controlled for in randomised controlled trials (RCTs). For example, electronic data may be inconsistently collected, with missing data elements that can result in reduced statistical validity. Similarly, adverse events are rarely captured in databases that act as data sources for real-world studies. Therefore, real-world evidence should be considered alongside the results of RCTs and the findings evaluated with appropriate caution. As seen in clinical trials, the most common side effects of Ozempic® include nausea, vomiting, diarrhoea, stomach (abdominal) pain, and constipation.

**For additional media materials, including video footage of the EXPERT and PATHWAY study investigators providing further context on the data, please visit:**
https://www.epresspack.net/novonordiskADA2020/

## About EXPERT

The GLP-1-Experienced Patients Switching to Once-Weekly Semaglutide in a Real-World Setting (EXPERT) study used prescription data from Explorys (IBM Watson Health) US medical records database (data cut-off 12/5/19). Adults with type 2 diabetes with ≥1 prescription for semaglutide (index/switch date), a prescription for any other GLP-1 RA (baseline) in the previous year, and separate $HbA_{1c}$/weight measurements at 6 and/or 12 months post-index and in the 90-day pre-index period were identified from the database. Participants with valid $HbA_{1c}$ (n=365) and weight (n=480) data were included in the study and had similar baseline characteristics.[2]

## About PATHWAY

The PATHWAY study compared treatment intensification options for glycaemic control in people with type 2 diabetes on two oral antidiabetic drugs (OADs). The PATHWAY study used linked electronic medical records and claims data from IBM MarketScan Explorys Claims-EMR (index period: 3/1/13–10/31/18). The study comprised two groups: the $HbA_{1c}$ cohort (n= 4,792) and the weight and composite endpoint analysis cohort (n = 3,927). Participants with ≥1 claim for 2 different OADs in the 180 days pre-index, ≥1 claim for another OAD/GLP-1 RA/insulin (index date), ≥1 $HbA_{1c}$ and/or weight measurement 180 days post-index, and ≥1 $HbA_{1c}$ and/or weight measurement close to index date (baseline) were included in the study. Cohorts for GLP-1 RAs vs OADs and vs insulin were propensity score matched pairwise by baseline variables and exact matched by $HbA_{1c}$ category, resulting in well balanced cohorts across all baseline characteristics.[1]

## About SUSTAIN clinical trial programme

The SUSTAIN clinical development programme for Ozempic® currently comprises 10 Phase 3 global clinical trials, including a cardiovascular outcomes trial, which included people with type 2 diabetes and high cardiovascular risk. The programme involves more than 10,000 adults with type 2 diabetes in total.[3-12]

## About Ozempic®

Ozempic® (once-weekly semaglutide) is an analogue of the naturally occurring hormone glucagon-like peptide-1 (GLP-1). It is administered in a once-weekly injection of 0.5 mg or 1 mg and indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes as well as to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease.[13] Ozempic® was first approved by the US FDA in 2017 and is now launched in 25 countries.

## 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 43,100 people*

*in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.*

**Further information**


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