company announcement

Rybelsus® (oral semaglutide) approved for the treatment of adults with type 2 diabetes in the EU

Bagsværd, Denmark, 4 April 2020 - Novo Nordisk today announced that the European Commission (EC) has granted marketing authorisation for Rybelsus® (oral semaglutide), for the treatment of adults with insufficiently controlled type 2 diabetes to improve glycaemic control as an adjunct to diet and exercise. The marketing authorisation applies to all 27 European Union member states and the United Kingdom.

Rybelsus® is the first and only oral glucagon-like-peptide-1 (GLP-1) receptor agonist. The approval is based on the results from 10 PIONEER clinical trials, in which Rybelsus® after 52 weeks demonstrated statistically significant reductions in HbA_{1c} vs sitagliptin, empagliflozin and liraglutide and with up to 4.3 kg weight reduction. Across the PIONEER programme, Rybelsus® demonstrated a safe and well-tolerated profile, with the most common adverse event being mild to moderate nausea which diminished over time.

"We are very excited about the approval of Rybelsus® as we can now offer people in Europe living with type 2 diabetes the first and only GLP-1 in a tablet," said Mads Krogsgaard Thomsen, executive vice president and chief science officer. "Based on its strong clinical profile, we believe Rybelsus® has the potential to set a new standard for the treatment of type 2 diabetes, as millions of people are currently not achieving target blood sugar levels on available oral antidiabetic medications."

The launch of Rybelsus® is expected to take place in the first EU countries in the second half of 2020.

About Rybelsus®
Rybelsus® (oral semaglutide) is an analogue of the naturally occurring hormone GLP-1. Rybelsus® is approved in the US, Switzerland and EU as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. It is administered once daily and is approved for use in two therapeutic dosages, 7 mg and 14 mg.

Rybelsus® is currently under review by several regulatory agencies, including the Japanese Pharmaceuticals and Medical Devices Agency.

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