company announcement

# Rybelsus® (semaglutide tablets), the first GLP-1 in a tablet approved in the US

**Bagsværd, Denmark, 20 September 2019 -** Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved Rybelsus® (semaglutide tablets), as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus.

Rybelsus®, the brand name for oral semaglutide in the US, is the first approved glucagon-like peptide-1 (GLP-1) receptor agonist in a tablet. The approval of Rybelsus® is based on the results from 10 PIONEER clinical trials which included 9,543 adults with type 2 diabetes. Rybelsus® more effectively lowered blood sugar than sitagliptin and empagliflozin. Furthermore, treatment with Rybelsus® resulted in up to 4.4 kg reduction in body weight. Rybelsus® demonstrated a safe and well-tolerated profile across the PIONEER programme, with the most common adverse event being mild to moderate nausea which diminished over time.

"We are very excited that we can make the first oral GLP-1 available in the US and thereby expand the treatment options for adults living with type 2 diabetes," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "Novo Nordisk has a very long legacy of developing innovative injectable medicines for people living with diabetes and, with the approval of Rybelsus®, we are now able to bring our innovation into the market for oral antidiabetics."

Novo Nordisk plans to make Rybelsus® available to adults with type 2 diabetes in the US in the fourth quarter of 2019.

## Conference call

On 23 September at 8 am CEST, corresponding to 2 am EDT, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

## About Rybelsus®

Rybelsus® (oral semaglutide) is an analogue of the naturally occurring hormone glucagon-like peptide-1 (GLP-1). Rybelsus® is the first and only GLP-1 receptor agonist

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(RA) in a tablet. 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 European Medicines Agency and the Japanese Pharmaceuticals and Medical Devices Agency. Furthermore, Rybelsus® has been applied for a separate indication with the FDA for the reduction of major adverse cardiovascular events in adults with type 2 diabetes and established cardiovascular disease, with expected review completion by Q1 2020.

*Novo Nordisk is a global healthcare company with more than 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 41,600 people in 80 countries and markets its products in more than 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.*

**Further information**

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